89-168

No. _____

Supreme Court, U.S.
FILED
JUL 31 1989
JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

REXALL DRUG COMPANY,

Petitioner,

—v.—

ELIZABETH TIGUE, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE COURT OF APPEALS OF THE STATE OF NEW YORK

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July 28, 1989

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QUESTIONS PRESENTED FOR REVIEW

1. Whether a state violates the Due Process Clause of the Fourteenth Amendment when it imposes liability on a company for injuries suffered by a person with whom it never came in contact and caused by a product it did not make?

2. Whether a state violates the supremacy clause by making a company liable to a plaintiff for simply engaging in an activity that the federal government authorized it to engage in, when that activity caused no harm to that plaintiff?

LIST OF PARTIES

The judicial decision that is the subject of this proceeding involved four separate appeals that were consolidated for argument and decision by the Court of Appeals of the State of New York. One of those four appeals is the subject of this petition. The parties involved in the subject case are:

Plaintiffs-Respondents:	Elizabeth Tigue; Barbara Tigue; and Sayre Margolies (as Administratrix of the Estate of Myrna Margolies).
Defendants-Appellants:	E.R. Squibb & Sons, Inc.; Abbott Laboratories; Merck, Sharpe & Dohme (a division of Merck & Co., Inc.); Rexall Drug Company; The Upjohn Company; William H. Rorer, Inc.; Boyle & Company Pharmaceuticals.
Defendants:	Amfre-Grant, Inc. (a subsidiary of Ormont Drug & Chemical Co., Inc.); Carnrick Laboratories (a division of G.W. Carnrick Co.); Cole Pharmaceutical Company, Inc.; Kremers-Urban Company; Jerome Schneider, M.D.

STATEMENT OF CORPORATE PARTY REQUIRED BY SUPREME COURT RULE 28.1

Rexall Drug Company, now known as RXDC Liquidating Trust, was dissolved on August 13, 1987.

At the time of its dissolution, RXDC Liquidating Trust had no parent, subsidiary or affiliate companies.

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REXALL DRUG COMPANY,

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ELIZABETH TIGUE, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE COURT OF APPEALS OF THE STATE OF NEW YORK

Rexall Drug Company ("Rexall") hereby petitions for a writ of certiorari to review the judgment of the Court of Appeals of the State of New York which held that a manufacturer, having absolutely no connection with a person allegedly injured by another manufacturer's product, would nevertheless be liable to that person simply because it made a similar product.

OPINIONS IN THE COURTS BELOW

The opinion of the Court of Appeals of the State of New York (Appendix at 1a; hereinafter the Appendix shall be referred to as "App.") is reported at 73 N.Y.2d 487, 541 N.Y.S.2d 941 (1989). The memorandum decision of the Appellate Division, First Department, of the Supreme Court of the State of New York (App. at 29a) is reported at 139 A.D.2d 431,

526 N.Y.S.2d 825 (1st Dep't 1988). The trial court's opinion denying Rexall's motion for summary judgment (App. at 32a) is reported at 136 Misc. 2d 467, 518 N.Y.S.2d 891 (Sup. Ct. N.Y. Co. 1987).

JURISDICTION

The opinion of the New York Court of Appeals was entered and filed April 4, 1989. None of the parties sought rehearing. The jurisdiction of this Court is invoked under 28 U.S.C. § 1257.

By order dated June 28, 1989, this Court extended to August 2, 1989, Rexall's time within which to file a petition for certiorari.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article VI of the United States Constitution provides in pertinent part:

> This Constitution, and the laws of The United States which shall be made in pursuance thereof . . . shall be the supreme law of the land; and the judges of every state shall be bound thereby . . . .

The Fourteenth Amendment to the United States Constitution provides in pertinent part:

> No State shall . . . deprive any person of life, liberty or property, without due process of law . . . .

The Federal Food, Drug, and Cosmetic Act of 1938, § 1 et seq., as amended, 21 U.S.C. § 301 *et seq.* (1989), and the regulations promulgated thereunder.

STATEMENT OF THE CASE

This is a New York State action in which respondents claim that they have been injured by their exposure to an unknown brand of Diethylstilbestrol ("DES"). Rexall proved in the trial court that respondents were not exposed to DES manufactured or distributed by Rexall. The trial court, however, denied Rexall's summary judgment motion, overruling all of Rexall's constitutional objections to the imposition of liability on it for damages caused by some other manufacturer's product. That decision was affirmed in a memorandum decision by the Appellate Division, First Department, which thereafter certified the appeal to the Court of Appeals of the State of New York. On April 4, 1989, the Court of Appeals dismissed, without discussion, Rexall's constitutional arguments and ruled that Rexall is liable to respondents and all other DES plaintiffs in New York, regardless of Rexall's undisputed showing that its product was not involved, simply because it manufactured and distributed a similar DES product, and not because it actually caused any injury to respondents.

A. Rexall

Petitioner Rexall was primarily a seller of a line of vitamin, toiletry and sundry products from 1903 until 1986. It also sold an assortment of generic over-the-counter and generic prescription pharmaceutical products[1] as a service to its affiliated pharmacies. Pursuant to a company policy that it maintained from 1903 to 1978, Rexall distributed its products only to "Rexall Drug Stores," a term used to denote pharmacies owned or franchised by Rexall. As a result of this policy, consumers could obtain Rexall products only from Rexall Drug Stores.

One of Rexall's generic prescription pharmaceutical products was DES. DES is a synthetic form of the female hormone estro-

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1 Generic prescription pharmaceutical products are products which are not patented and which may be manufactured and marketed by anyone once they have received approval from the Food and Drug Administration ("FDA"). Penicillin is perhaps the most common example of such a product.

gen. Rexall manufactured its DES by purchasing the active chemical in bulk form and by combining that active chemical with numerous other ingredients of its own choosing. Rexall's DES was available for distribution through Rexall Drug Stores from 1943 through 1969.

B. The Development, Testing And Governmental Approval Of DES

DES was invented in the late 1930's by a team of English researchers working independently of any pharmaceutical company. The synthesis of DES was considered a revolutionary breakthrough in the field of estrogen research because DES could be used effectively in all therapies where natural estrogen had previously been used, was inexpensive and, unlike natural estrogens, could be administered orally. DES made estrogen therapy available to all women for the first time. The formula for DES, although published, was never patented. *See generally Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004, 1008-1009 (D.S.C. 1981); *Payton v. Abbott Laboratories*, 512 F. Supp. 1031, 1032 (D. Mass. 1981).

Before any company could distribute DES products in the United States, it was required to submit a New Drug Application ("NDA") to the FDA[2] pursuant to the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 *et seq.* Pursuant to stringent requirements imposed by the FDA, each NDA had to include a detailed description of the chemical composition and proposed uses of the drug, clinical data establishing its safety and efficacy, methods of manufacturing and proposed labeling. In 1941, the FDA granted approval to ten pharmaceutical companies to market DES products for non-pregnancy related uses.

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2 The FDA has been recognized as "the most effective national drug regulatory agency in the world." Stulley, *Assuring the Safety and Efficacy of Therapies*, 4 Int'l J. of Health Services 131, 142 (1974). The FDA "probably requires the most careful drug safety testing of any regulatory agency in the world." Simmons, *The Drug Regulatory System of the United States Food and Drug Administration*, 4 Int'l J. of Health Services 95, 97 (1974).

During the mid-1940's, reports by independent physicians of the successful use of DES products to treat problem pregnancies appeared in the medical literature. Beginning in 1947, numerous pharmaceutical companies sought FDA approval to indicate DES products for use in the treatment of accidents of pregnancy. After a thorough review of the manufacturers' applications and additional independent research of its own, the FDA granted initial approval for the manufacturing and marketing of DES products for pregnancy-related uses in July 1947. Thereafter, in 1948, Rexall filed its own NDA and was granted approval to manufacture and distribute its DES product. In 1952, the FDA concluded that DES was no longer a "new drug" within the meaning of 21 U.S.C. § 355(a). It was "generally recognized as safe" for all of its previously approved uses, including its use in the treatment of accidents of pregnancy.[3] *Ryan v. Eli Lilly & Co., supra*, 514 F. Supp. at 1011 n.3. After that determination, any company following approved manufacturing practices could market DES without filing an NDA.

Ultimately, more than 300 companies distributed different products that have been loosely lumped together under the name DES. *Id.* at 1010-1011. The one constant in this group of products was the formula for the active ingredient, which was, and continues to be, dictated by an official government compendium, the United States Pharmacopoeia. However, the active chemical ingredient in DES, as in most prescription pharmaceutical products, accounts for less than 10% of the product. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983). A product's so-called inactive ingredients and binders account for the remaining 90% of the product. These other ingredients interact with the product's active ingredient causing a significant increase or decrease in the bioavailability of the

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3 DES was not the only product indicated for use in the treatment of accidents of pregnancy during this time period. The 1953 Physicians Desk Reference lists numerous other synthetic estrogens as well as non-synthetic estrogens and progesterones which were indicated for this purpose. These products include benzestrol, dienestrol, hi-bestrol, tristerone, proluton, progestin, promentron and cyclogesterin. *See Physicians Desk Reference* at 424, 488-489, 511-512, 536, 563 (7th ed. 1953).

active ingredient. Among the multitude of factors that can considerably affect a product's action and bioavailability are coatings, lubricants, binders and emulsifying agents, all of which, together with differences in the manufacturing processes, guaranteed that each manufacturer's DES was different, and quite possibly materially so. *See United States v. Premo Pharmaceutical Laboratories, Inc.*, 511 F. Supp. 958, 962-65 (D.N.J. 1981). In addition, the FDA permits a 30% variation, plus or minus, between brand name drugs and their generics. This variation means that different brands of the same drug, including DES, can have different effects and safety levels because there may be a spread of 60% between the bioavailability of one DES product and another. *See* Schwartz, *Anticonvulsant Drug Substitution, Is There a Health Care Tradeoff? An Overview of the Issues Involving Generic and Therapeutic Substitution* (Epilepsy Institute); Schwartz, *The Debate Over Substitution Policy, Its Evolution and Scientific Basis*, The American Journal of Medicine, Vol. 79 (Suppl. 2B) (August 23, 1985).

C. DES From 1971 To Present

DES was used until 1971 for its many purposes without any reported incidents of adverse effects. In 1971, Dr. Arthur Herbst published an article purporting to show a statistical association between *in utero* exposure to DES and the development of a rare form of cancer, clear cell adenocarcinoma of the vagina, in young women. Herbst, *Adenocarcinoma of the Vagina—Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women*, 284 New Eng. J. Med. 871 (1971). Primarily as a result of this preliminary retrospective study, the FDA required drug companies not to indicate DES for use in the treatment of accidents of pregnancy. DES continues to be used today for many of its other originally approved uses.

Despite numerous efforts to obtain the raw data relied upon by Herbst, it has never been made available to the medical profession for review. *Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 560, 563 (7th Cir. 1984). Dr. Herbst's hypothesis of a statistical association between DES and harmful effects has

never been substantiated. *See, e.g.*, Mantel, "Some Problems with Investigations and Epidemiological Studies Relating to Pregnancy," in *Prevention of Physical and Mental Congenital Defects*, pp. 45-48 (M. Marois ed. 1985); McFarlane, *Diethylstilbestrol and Clear Cell Vaginal Carcinoma*, 81 Am. J. Med. 855 (1986).

Moreover, since the Herbst study, it has been established that clear cell adenocarcinoma of the vagina and cervix occurred long before the synthesis of DES and that it also occurs naturally in women who were never exposed to DES. *See, e.g.*, Kaminski, *Clear Cell Adenocarcinoma of the Cervix Unrelated to Diethylstilbestrol Exposure*, 62 Obstetrics & Gynecology 720 (1983); Melnick, *Rates and Risks of Diethylstilbestrol-Related Clear-Cell Adenocarcinoma of the Vagina and Cervix*, 316 New Eng. J. Med. 514 (1987).

D. The Tigue Case

Elizabeth Tigue and Myrna Margolies filed suit in 1976 alleging injuries from DES.

1. Elizabeth Tigue

Elizabeth Tigue ("Tigue") alleges that she suffers from adenosis, a common benign tissue condition, as a result of her mother's ingestion of DES in 1960 while pregnant with her. Tigue is unable to identify the specific pharmaceutical company that manufactured her mother's DES. However, Tigue's parents testified that the DES to which Tigue was exposed was obtained from either Platt Drugs in Bayside, New York, or Korvettes in Manhattan, New York. It is undisputed that neither of these stores was ever a Rexall Drug Store. Thus, Tigue's mother could not have ingested DES manufactured, distributed or sold by Rexall.

2. Myrna Margolies

Sayre Margolies ("Margolies"), as administratrix of the estate of her daughter, Myrna Margolies, asserts a claim for wrongful death. Margolies claims her daughter's cancer

resulted from Margolies' ingestion of DES in 1953 while pregnant with her.

Margolies and her husband both testified that her DES prescription was filled at Praisner's Pharmacy in Brooklyn, New York. It is undisputed that Praisner's Pharmacy was never a Rexall Drug Store, a fact confirmed by the testimony of the pharmacist who owned Praisner's when Margolies' prescription allegedly was filled. Thus, Margolies, like Tigue's mother, could not have ingested Rexall's DES product.

E. Resolution Of The Federal Issues In The New York Supreme Court And In The Appellate Division, First Department

In December 1986, Rexall moved for summary judgment. Under all traditional product liability theories then in force in the State of New York and all non-identification liability theories that had been adopted elsewhere,[4] Rexall argued that it was

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4 The majority of jurisdictions adhere to the usual view that identification of the manufacturer is required in a DES case. *Mulcahy v. Eli Lilly & Co.*, 386 N.W.2d 67 (Iowa 1986); *Burnside v. Abbott Laboratories*, 351 Pa. Super. 264, 505 A.2d 973 (1985); *Zafft v. Eli Lilly & Co.*, 676 S.W.2d 241 (Mo. 1984); *Tidler v. Eli Lilly & Co.*, 851 F.2d 418 (D.C. Cir. 1988); *Morton v. Abbott Laboratories*, 538 F. Supp. 593 (M.D. Fla. 1982); *Mizell v. Eli Lilly & Co.*, 526 F. Supp. 589 (D.S.C. 1981); *Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004 (D.S.C. 1981); *Payton v. Abbott Laboratories*, 512 F. Supp. 1031 (D. Mass. 1981); *Gray v. United States*, 445 F. Supp. 337 (S.D. Tex. 1978); *Lyons v. Premo Pharmaceutical Labs., Inc.*, 170 N.J. Super. 183, 406 A.2d 185, *certif. denied*, 82 N.J. 267, 412 A.2d 774 (1979); *Namm v. Charles E. Frosst & Co.*, 178 N.J. Super. 19, 427 A.2d 1121 (1981); *Pipon v. Burroughs-Wellcome Co.*, 532 F. Supp. 637 (D.N.J. 1982), *aff'd*, 696 F.2d 984 (3d Cir. 1982). *But see Shackil v. Lederle Laboratories*, 219 N.J. Super. 601, 530 A.2d 1287 (App. Div.), *certif. granted*, 109 N.J. 519, 537 A.2d 1304 (1987).

The non-identification liability theories began with *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, *cert. denied*, 449 U.S. 912 (1980). In addition to *Sindell* in California, three other state courts have adopted some form of non-identification liabil-

entitled to summary judgment because it had demonstrated that it did not manufacture the DES which allegedly caused the injuries in this case. (App. at 37a).

Rexall further contended that the adoption of any novel theory of liability that eliminated the need to establish a connection between the allegedly injured party and the party that allegedly caused the injury violated the due process, equal protection, supremacy, and commerce clauses of the United States Constitution. (App. at 37a-39a). The trial court rejected all of Rexall's arguments and denied the motion. (App. at 38a-39a). In a memorandum decision that did not address Rexall's constitutional arguments (*see* App. at 50a-58a), the New York Supreme Court, Appellate Division, First Department, affirmed the trial court's ruling. (App. at 29a-30a).

F. The Decision Of The New York Court Of Appeals

Tigue was certified by the Appellate Division to the Court of Appeals of the State of New York. On appeal, Rexall again argued that it was unconstitutional to impose liability on it in circumstances where it had proved it did not manufacture the product that allegedly harmed the plaintiffs. (App. at 40a-49a). Thereafter, *Tigue* was consolidated for argument and decision with appeals from denials of summary judgment motions made by defendants in three other DES cases.

On April 4, 1989, the Court of Appeals issued its opinion. The majority opinion, to which four justices subscribed, eliminated any need for plaintiffs to identify the defendant who

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ity in DES cases in which the burden of identifying the manufacturer of the allegedly harmful product is shifted to the defendants, and a defendant is allowed to exculpate itself by showing that its product could not have caused the alleged harm. *See Collins v. Eli Lilly & Co.*, 116 Wis. 2d 166, 342 N.W.2d 37, *cert. denied sub nom. E.R. Squibb & Sons, Inc. v. Collins*, 469 U.S. 826 (1984); *Abel v. Eli Lilly & Co.*, 418 Mich. 311, 343 N.W.2d 164, *cert. denied*, 469 U.S. 833 (1984); *Martin v. Abbott Laboratories*, 102 Wash. 2d 581, 689 P.2d 368 (1984). Only in New York, as a result of the instant case, can a company be liable even though it is undisputed that its product did not injure a given plaintiff.

manufactured the DES ingested. Instead, the majority decided to create a theory that the dissent characterized as a "radical departure from fundamental tenets of tort law" which is "unnecessarily unfair and inequitable to the defendants who have proven, or can prove, that they did not produce the pill which caused the injury." (App. at 22a).

What the Court of Appeals adopted is an extreme version of the "market share" theory of liability.[5] That new theory imposes liability on all manufacturers of DES products to the extent of their respective market share if their DES was indicated for use during pregnancy. (App. at 12a-13a). No consideration is given to "whether the defendant drug companies actually caused the plaintiff's injuries." (App. at 22a).

Unlike every other court that has adopted a non-identification theory of liability,[6] the Court of Appeals refused to allow manufacturers to "exculpate" themselves by proving that the product which they made could not have caused the plaintiffs' injury. Instead, the majority presumed the "culpability" of all DES manufacturers simply on the basis of their "marketing the product." (App. at 13a). The Court specifically acknowledged that its theory did *not* "provide a reasonable link between liability and the risk created by a defendant to a particular plaintiff" (App. at 12a) and justified its refusal to permit

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5 The "market share" theory was first propounded by the California Supreme Court in *Sindell*. The *Sindell* Court was faced with the situation in which a plaintiff, allegedly injured by DES, could not identify the manufacturer of the DES that was ingested by her mother, but could arguably satisfy all of the other elements of her tort claim. The *Sindell* Court shifted the burden of identifying the ingested DES to the drug manufacturers, who were required to exculpate themselves by showing that they did not produce the DES in question. The manufacturers who failed to prove that their DES did not cause plaintiff's injuries would be liable for a percentage of plaintiff's damages equal to their market share of DES at the time the plaintiff's mother ingested DES. 26 Cal. 3d at 612-13, 607 P.2d at 937, 163 Cal. Rptr. at 145. *See also Brown v. Superior Court (Abbott Laboratories)*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

6 *See* notes 4 and 5, *supra*.

exculpation "because liability here is based on the over-all risk produced" and "not causation in a single case." (App. at 13a).

The dissenting Justice could not, however, reconcile the majority's radical theory of liability that eliminated a "fundamental causative factor as a basis for recovery" (App. at 24a) with basic principles of fairness and tort law:

> I cannot agree that the imposition of liability on drug companies . . . without any consideration given to whether the defendant drug companies actually caused the plaintiff's injuries, is appropriate or warranted.
>
> * * *
>
> [T]he majority fails to perceive that this is no more and no less than a basic principle of tort law; i.e., a plaintiff may not recover for his or her injuries from a defendant who could not have caused those injuries.

(App. at 22a, 24a).

In accordance with its understanding of the law, the dissent concluded that, based on Rexall's "uncontroverted evidence demonstrating Rexall's noninvolvement in these plaintiffs' injuries, Rexall's motion for summary judgment should have been granted." (*See* App. at 25a).

SUMMARY

This case presents a constitutional issue of first impression: whether a defendant manufacturer can be held liable for personal injuries allegedly caused by a product that defendant has proved it did not manufacture. For the very first time, a state court has said a plaintiff may recover from such a manufacturer even though it had absolutely no connection with the product which injured that plaintiff. The question perforce arises as to whether it is constitutionally permissible to deprive a defendant of property without a showing that the defendant is causally or reasonably related to the injury.

This case also presents a second constitutional issue: whether a state-created cause of action is preempted when that cause of action is founded on and indeed arises solely from an activity that had been expressly sanctioned by the FDA—the manufacture and distribution of a product—where that product caused no injury to the plaintiffs.

REASONS FOR GRANTING THE WRIT

I

CERTIORARI IS APPROPRIATE BECAUSE ALL FEDERAL ISSUES HAVE BEEN FINALLY DECIDED AND DELAY IN REVIEW WILL SERIOUSLY ERODE FEDERAL POLICY

This Court has jurisdiction to hear this case under 28 U.S.C. § 1257 authorizing review of "[f]inal judgments or decrees rendered by the highest court of a State in which a decision could be had . . . where any title, right, privilege or immunity is . . . claimed under the Constitution. . . ."

The judgment of the Court of Appeals is final within the meaning of Section 1257 because that Court has considered and rejected Rexall's constitutional arguments. While the case has been remanded to the trial court for further proceedings in accordance with the Court of Appeals decision, Rexall has heard that Court's "last word on the constitutionality" of its radical theory of market share liability. *Duquesne Light Co. v. Barasch*, ____ U.S. ____, 109 S. Ct. 609, 614-15 (1989). Now Rexall faces the prospect and prohibitive financial burden of defending itself in hundreds of lawsuits where its product was not involved, a need that would have been obviated if its constitutional rights had been vindicated.[7] In circumstances similar to these, this Court has time and again held that the "finality" requirements of Section 1257 have been satisfied and that review is appropriate. *See, e.g., Shaffer v. Heitner*, 433 U.S. 186, 195-96 n.12 (1977); *Cox Broadcasting Corp. v. Cohn*, 420

7 There are currently between 700 and 1000 plaintiffs who have DES cases pending in New York State.

U.S. 469, 485 (1975); *American Motorists Ins. Co. v. Starnes*, 425 U.S. 637, 642 n.3 (1976).

Review by this Court is further compelled by the fact that the decision below has resulted in a serious erosion of federal policy. *Cox, supra*, 420 U.S. at 482-483. The majority's ruling that a defendant is liable for the manufacture and distribution of a DES product, without more, flies squarely in the face of the FDA's prior authorization of those activities and directly implicates the deep, abiding federal interest in the development and use of pharmaceuticals as evidenced by, *inter alia*, the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (1989).

II

THIS COURT SHOULD CONSIDER WHETHER NEW YORK HAS ARBITRARILY IMPOSED LIABILITY ON REXALL IN VIOLATION OF THE DUE PROCESS CLAUSE OF THE CONSTITUTION

A state court's creation of state tort law, like all law created in this country, is bounded by the limits of the Due Process Clause. *Martinez v. California*, 444 U.S. 277, 282 (1980); *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 429-33 (1982); *NAACP v. Alabama*, 377 U.S. 288, 307-08 (1964). *See also Martin v. Hunter's Lessee*, 14 U.S. (1 Wheat) 304 (1816). When a state court issues a decision that is "wholly arbitrary or irrational," *Martinez v. California, supra*, or that conflicts with those "fundamental 'principles which have been established in our systems of jurisprudence for the protection and enforcement of private rights,' " *American Ry. Express Co. v. Kentucky*, 273 U.S. 269, 273 (1927), *quoting Pennoyer v. Neff*, 95 U.S. 714, 733 (1877), it violates due process and must be overturned.

The due process right that Rexall seeks to vindicate here is simple and fundamental: the right to be free from an admittedly irrational and arbitrary state court decision that unfairly deprives it of its property. Rexall has demonstrated that it did not make, sell or distribute the products alleged to have harmed

respondents. It can make a similar demonstration in hundreds of the more than 500 DES cases pending in New York. Yet, if this Court does not act to correct the arbitrary and irrational decision of the Court of Appeals, Rexall will be held liable in damages to respondents in this case and to hundreds of plaintiffs in other DES cases. That liability is nothing less than an unconstitutional deprivation of Rexall's property for wrongs that it has not committed. *See Murray's Lessee v. Hoboken*, 59 U.S. 372 (1856). *Cf. Robinson v. California*, 370 U.S. 660, 679 (1961) (Harlan, J. concurring); *Jackson v. Virginia*, 443 U.S. 307, 314 (1978); *Vachon v. New Hampshire*, 414 U.S. 478 (1974).

In these circumstances, this Court must issue a writ of certiorari so that the constitutionality of the radical theory of liability created by the New York Court of Appeals can be considered.

A. The New York Court Of Appeals' Radical Theory Of Liability Violates Due Process By Conclusively Presuming Liability

The reasoning used by the Court of Appeals to justify its decision plainly shows the decision's constitutional deficiencies. First, the Court of Appeals flatly admits that the theory of liability it has constructed contains no "reasonable link between liability and the risk created by a defendant to a particular plaintiff." (App. at 12a). It further admits that its theory is not "founded upon the belief that, over the run of cases, liability will approximate causation." (App. at 12a). Instead, "for essentially practical reasons," the Court of Appeals states that "we choose to apportion liability" on a market share basis "so as to correspond to the over-all culpability of each defendant." (App. at 12a). "Culpability," in the view of the Court of Appeals, attaches without fail to each and every manufacturer and distributor of DES simply because it was "a member of the market producing DES for pregnancy use." (App. at 13a).

The heart of the constitutional violations committed by the Court of Appeals lies in the above-quoted statements. Rationality, the "touchstone" of due process, is discarded and in its

stead is put a presumption of the Court's own invention, a presumption that is as conclusive and irrebuttable as it is wrong. The Court presumes that Rexall is liable simply and solely because it is a former manufacturer and distributor of DES. No negligence in the manufacture or distribution of the drug, nor any failure to act, plan or warn underlies the Court's presumption of Rexall's liability. Rather it is Rexall's status as a DES manufacturer, and this status alone, which has given rise to a conclusive presumption of liability, and the Court's use of this rationale presents, at a minimum, three serious constitutional questions.

First, it is completely inappropriate, and contrary to our system of justice, to base a conclusive presumption of liability on a party's status. *Cf. Robinson v. California*, *supra*, 370 U.S. at 678-79. No court would allow such a presumption to be founded upon one's economic standing, one's job, one's residence, one's religious beliefs or the color of one's skin. This Court long ago outlawed the use of a "badge of infamy" to deprive a party of his or her life, liberty or property, and the Court of Appeals' attempt to resuscitate such a practice simply cannot stand constitutional scrutiny. *See Joint Anti-Fascist Refugee Committee v. McGrath*, 341 U.S. 123, 162-74 (1951) (Frankfurter, J. concurring).

Second, a conclusive and irrebuttable presumption, such as the one adopted by the highest court of the State of New York, is constitutionally invalid unless it can be shown that the presumption is "necessarily or universally true in fact." *Cleveland Board of Education v. La Fleur*, 414 U.S. 632, 644 (1974); *Vlandis v. Kline*, 412 U.S. 441, 452 (1973); *Stanley v. Illinois*, 405 U.S. 645, 656-57 (1972). There has been no demonstration in this or any other case that any wrongdoing should be ascribed to the mere manufacture and distribution of DES—particularly when that was an activity expressly authorized by the FDA.[8]

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8 It cannot seriously be contended that Rexall or any other drug manufacturer or distributor was engaged in an activity that, by its very nature, was harmful to society. Indeed, the opposite is undeniably true. Nevertheless, decisions like the one below have hindered, and in some cases, prevented the availability of useful, life-saving drugs in the

Nor is there any "rational connection" between the fact proved—that Rexall manufactured and distributed DES—and the conclusion of law presumed—that Rexall is now liable to all those who may have been injured by DES without regard to whether it was Rexall's DES that caused that harm. *Leary v. United States*, 395 U.S. 6, 32-37 (1969). *See Tot v. United States*, 319 U.S. 463 (1943).

Furthermore, the Court's unfounded presumption of Rexall's "culpability" by reason of Rexall's status necessarily contains at least two additional presumptions that are similarly unfounded. To reach its conclusive presumption of liability, the Court further presumed (i) that all manufacturers and distributors engaged in precisely the same conduct[9] and (ii) that all DES

United States. *See* Huber, *Liability: The Legal Revolution and its Consequences*, pp. 1-18 (Basic Books, 1988) (because of the tort system, a drug for treating rare stomach disorders is unavailable; 95% of cost of childhood vaccines attributed to insurance and other costs of litigation; safe contraceptives unavailable while "tried and true" contraceptives—not as safe or effective as new ones—remain on the market); *New York Times*, October 14, 1986, Section C at 1, col. 2 (patients with rare neuromuscular disorders are caused to suffer additional complications when their supply of experimental medicine was cut off when its only manufacturer was unable to obtain product liability insurance); Grabowski, *Drug Regulation and Innovation: Empirical Evidence and Policy Options*, 1976 (increased costs of marketing resulting from tort claims cost the public an estimated $300 million and thousands of lives).

9 The court's presumption that all DES manufacturers were the same is incorrect. Each of the approximately 300 manufacturers that produced DES has its own unique story regarding its role in the development, manufacture, marketing or distribution of DES. For example:

- some manufacturers sold DES under its generic name, but many sold it under proprietary brand names;
- some manufacturers advertised DES, some did not;
- some manufacturers tested DES, some did not;
- some manufacturers dealt directly with doctors, most did not;
- some manufacturers filed NDAs, most did not;
- some manufacturers made the active ingredient, most did not;
- some manufacturers filed supplemental NDA's, most did not;
- some manufacturers coated their DES tablets, others did not.

was alike.[10] Nothing could be further from the truth. The record below shows that each manufacturer's involvement with DES and the DES each produced was distinct and different. Yet the Court of Appeals, in transforming its own beliefs into conclusive, irrebuttable presumptions, ignored the facts that tended to contradict those presumptions, and chose, like Procrustes, to alternatively chop and stretch to make all DES manufacturers fit into its bed of liability.

Third, as is evident from the manner in which the conclusive and irrebuttable presumptions were adopted by the Court of Appeals, the procedural aspects of Rexall's due process rights have been infringed as well. As recently stated by this Court, "[a]n essential principle of due process is that deprivation of life, liberty, or property 'be preceded by notice and opportunity for hearing . . . .' " *Cleveland Board of Education v. Loudermill*, 470 U.S. 532, 542 (1985), *quoting Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 313 (1950); *Groppi v. Leslie*, 404 U.S. 496, 502 (1971); *Grannis v. Ordean*, 234 U.S. 385, 394 (1914). Rexall has had no such notice or opportunity to defend itself against conclusive presumptions of culpability that were adopted, *sua sponte*, by the highest court of the State of New York. Instead of absolving Rexall of liability as it should have done, the Court of Appeals imposed liability on it without a hearing, thereby denying Rexall the procedural due process to which it was entitled.

B. Due Process Does Not Permit The Imposition Of Liability On A Petitioner Who Had Absolutely No Connection To The Alleged Injury

The unfounded presumptions of the New York Court of Appeals, together with its refusal to allow Rexall to exculpate itself by showing that its product did not cause the alleged harm

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10 The only thing these DES products have in common is that each contains a synthetic estrogen. *See* pp. 5-6, *supra*. But synthetic estrogen is not unique to DES. There were dozens of other estrogen products used to treat accidents of pregnancy. *See* note 3, *supra*. Yet, these products are totally and inexplicably excluded from the artificial and arbitrary DES market.

in this or any other case, unfairly deprived Rexall, an innocent party with respect to the plaintiffs in this case, of its property. *See Payton v. Abbott Laboratories*, 386 Mass. 540, 572-73, 437 N.E.2d 171, 189 (1982); *Tidler v. Eli Lilly & Co.*, 95 F.R.D. 332, 334 (D.D.C. 1982), *aff'd*, 851 F.2d 418 (D.C. Cir. 1988).

Liability in tort in our common law system of justice is premised on the notion "that there be some reasonable connection between the act or omission of the defendant and the damage the plaintiff has suffered." W. Prosser & P. Keeton, *The Law of Torts*, § 41 at 263 (5th ed. 1984). As Justice Cardozo stated many years ago, "[p]roof of negligence in the air, so to speak, will not do." *Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 341, 162 N.E. 99 (1928). In accordance with these fundamental principles, no case, other than the one at bar, permits the imposition of liability on a demonstrably innocent party who had absolutely no connection with the allegedly injured plaintiff.

Modern courts, crushed by the weight of their caseloads, must be sorely tempted to do as the Court of Appeals has done, and create a system that imposes liability on the innocent in an effort to resolve expediently some of the most difficult disputes that tax them. But it is the role of this Court to ensure that whatever innovative systems are created satisfy the fundamental and elemental concerns of the Due Process Clause. Among the freedoms protected by the Due Process Clause must be the right not to be deprived of property when one has had absolutely no dealings or connection with the allegedly injured party who, if injured at all, was injured by someone else's product. Imposition of liability in those circumstances defies not just reason and logic but is completely contrary to the "deep-rooted demands of fair play enshrined in the Constitution." *Joint Anti-Fascist Refugee Committee v. McGrath*, *supra*, 341 U.S. at 161.

III

THIS COURT SHOULD CONSIDER WHETHER THE THEORY OF LIABILITY CREATED BY THE COURT OF APPEALS IS PREEMPTED BY FEDERAL REGULATION OF THE DRUG INDUSTRY

Ignored by the Court of Appeals, with all of Rexall's other constitutional arguments, was the argument that state law tort actions against Rexall are federally preempted. (App. at 47a-49a). The radical theory of liability created by the Court of Appeals' opinion now compels that serious consideration be given to the preemption doctrine.

The Court of Appeals has imposed liability on Rexall solely by reason of its manufacture and distribution of a DES product. Significantly, Rexall is not being held liable because it did something wrong with respect to plaintiff or because it acted in concert with somebody else who did something wrong to plaintiff. Rexall is being held liable simply because it engaged in an activity that it could not have engaged in but for federal approval. The imposition of liability for precisely that activity which was sanctioned by the federal government violates, in no uncertain terms, the supremacy clause.

The Federal Food, Drug, and Cosmetic Act of 1938 (the "Act") empowers the FDA to regulate the licensing, testing, production, distribution, review and approval of all new and existing drugs. Pursuant to that authority, the FDA determined DES to be safe and approved it for manufacture and distribution. Any state tort law action, like the one at bar, that bases liability merely on FDA approved manufacture and distribution is in direct and irreconcilable conflict with federal law. *See, e.g., Pharmaceutical Soc. of State of New York v. Lefkowitz*, 586 F.2d 953 (2d Cir. 1978) (the initial determination, and subsequent control in the marketplace, of the safety and efficacy of drugs are functions of the FDA which States are barred from regulating); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989).

Those lower court cases that have found no preemption of state tort law claims under the Act have done so in the belief that the activity at issue was not directly regulated, *see, e.g., MacGillivray v. Lederle Lab. Div. of American Cyanamid*, 667 F. Supp. 743 (N.D.N.M. 1987), or that the Act did not preempt a state court action based on actual wrongdoing by a defendant, such as a failure to warn. *See, e.g., Hurley v. Lederle Lab. Div. of American Cyanamid*, 851 F.2d 1536 (5th Cir. 1988). Even if these cases are correct, they are simply not applicable to the case at bar where the Court of Appeals' opinion has created liability premised solely on a comprehensively federally regulated and approved activity. Such liability cannot be imposed without violating the supremacy clause.

CONCLUSION

On the basis of the foregoing argument and authorities, and pursuant to Supreme Court Rule 17, petitioner respectfully requests that this petition for certiorari be granted.

Respectfully submitted,

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APPENDIX

STATE OF NEW YORK
COURT OF APPEALS

HYMOWITZ v LILLY & CO. [73 NY2d 487]

MINDY HYMOWITZ, Respondent v ELI LILLY AND COMPANY et al., Appellants, el al., Defendants. ATTORNEY-GENERAL OF THE STATE OF NEW YORK, Intervenor-Respondent.

ELIZABETH TIGUE et al., Respondents, v E. R. SQUIBB & SONS, INC., et al., Appellants, et al., Defendants.

JANE DOLAN et al., Respondents, v ELI LILLY AND COMPANY et al., Appellants. (And Other Actions.)

BARBARA HANFLING et al., Respondents, v ELI LILLY AND COMPANY et al., Appellants, et al., Defendants.

Argued February 15, 1989; decided April 4, 1989

OPINION OF THE COURT

Chief Judge WACHTLER.

[1-4] Plaintiffs in these appeals allege that they were injured by the drug diethylstilbestrol (DES) ingested by their mothers during pregnancy. They seek relief against defendant DES manufacturers. While not class actions, these cases are representative of nearly 500 similar actions pending in the courts in this State; the rules articulated by the court here, therefore, must do justice and be administratively feasible in the context of this mass litigation. With this in mind, we now resolve the issue twice expressly left open by this court, and adopt a market share theory, using a national market, for determining liability and apportioning damages in DES cases in which identification of the manufacturer of the drug that injured the plaintiff is impossible (*see*, *Kaufman v Lilly & Co.*, 65 NY2d 449, 456; *Bichler v Lilly & Co.*, 55 NY2d 571, 580). We also hold that the Legislature's revival for one year of actions for injuries caused by DES that were previously barred by the Statute of Limita-

tions (*see*, L 1986, ch 682, § 4) is constitutional under the State and Federal Constitutions.

I.

The history of the development of DES and its marketing in this country has been repeatedly chronicled (*see, e.g., Bichler v Lilly & Co., supra*; *Martin v Abbott Labs*, 102 Wash2d 581, 689 P2d 368; *Sindell v Abbott Labs*, 26 Cal 3d 588, 607 P2d 924, *cert denied* 449 US 912; Sheiner, *DES and a Proposed Theory of Enterprise Liability*, 46 Ford L Rev 963). Briefly, DES is a synthetic substance that mimics the effect of estrogen, the naturally formed female hormone. It was invented in 1937 by British researchers, but never patented.

In 1941, the Food and Drug Administration (FDA) approved the New Drug Applications (NDA) of 12 manufacturers to market DES for the treatment of various maladies, not directly involving pregnancy. In 1947, the FDA began approving the NDAs of manufacturers to market DES for the purpose of preventing human miscarriages; by 1951, the FDA had concluded that DES was generally safe for pregnancy use, and stopped requiring the filing of NDAs when new manufacturers sought to produce the drug for this purpose. In 1971, however, the FDA banned the use of DES as a miscarriage preventative, when studies established the harmful latent effects of DES upon the offspring of mothers who took the drug. Specifically, tests indicated that DES caused vaginal adenocarcinoma, a form of cancer, and adenosis, a precancerous vaginal or cervical growth.

Although strong evidence links prenatal DES exposure to later development of serious medical problems, plaintiffs seeking relief in court for their injuries faced two formidable and fundamental barriers to recovery in this State; not only is identification of the manufacturer of the DES ingested in a particular case generally impossible, but, due to the latent nature of DES injuries, many claims were barred by the Statute of Limitations before the injury was discovered.

The identification problem has many causes. All DES was of identical chemical composition. Druggists usually filled pre-

scriptions from whatever was on hand. Approximately 300 manufacturers produced the drug, with companies entering and leaving the market continuously during the 24 years that DES was sold for pregnancy use. The long latency period of a DES injury compounds the identification problem; memories fade, records are lost or destroyed, and witnesses die. Thus the pregnant women who took DES generally never knew who produced the drug they took, and there was no reason to attempt to discover this fact until many years after ingestion, at which time the information is not available.

We recognized this predicament in *Bichler v Lilly & Co.* (*supra* at 579), where the Court stated that in DES cases it is a "practical impossibility for most victims [to] pinpoint * * * the manufacturer directly responsible for their particular injury." We allowed plaintiff's recovery in that case, however, notwithstanding the failure of the plaintiff to identify the manufacturer of the injurious DES, on the limited basis that "the evidence was legally sufficient to support the jury verdict for the plaintiff" on the law as charged to the jury, and unobjected to by the defendant (see, *Kaufman v Lilly & Co.*, 65 NY2d 449, 456, *supra*). The question, therefore, of whether non-identification of the manufacturer precludes plaintiffs from recovering for DES caused injuries, remained unresolved after *Bichler v Lilly & Co.* (*supra*).

The second barrier to recovery, involving the Statute of Limitations, arose from the longstanding rule in this State that the limitations period accrued upon exposure in actions alleging personal injury caused by toxic substances (*Fleishman v Lilly & Co.*, 62 NY2d 888, *cert denied* 469 US 1192). In *Fleishman v Lilly & Co.* (*supra*) it became clear that this exposure rule led to many DES cases being barred by the Statute of Limitations before the discovery of injury; we held, however, that any change in the accrual date from exposure to discovery was more properly the prerogative of the Legislature (*id.* at 890; *see*, *id.* at 891 [Cooke, Ch. J., dissenting]). Two years after *Fleishman v Lilly & Co.* the Legislature addressed the Statute of Limitations problem, and instituted a discovery rule for "the latent effects of exposure to any substance" (L 1986, ch 682, § 2). The Legis-

lature also, for one year, revived causes of action for exposure to DES that had been time barred (L 1986, ch 682, § 4).

It is estimated that eventually 800 DES cases will be brought under the revival portion of this recent statute. Moreover, as indicated in *Bichler v Lilly & Co.* (*supra*), and as apparent from the record now before the Court, in the vast majority of these cases identification of the manufacturer of the DES that injured the plaintiff will be impossible. The Legislature, however, while reviving these time-barred actions, did not resolve the identification problem.

The present appeals are before the Court in the context of summary judgment motions. In all of the appeals defendants moved for summary judgment dismissing the complaints because plaintiffs could not identify the manufacturer of the drug that allegedly injured them. In three of the appeals defendants also moved on statute of limitations grounds, arguing that the revival of the actions was unconstitutional under the State and Federal Constitutions, and that the complaints, therefore, are time barred and should be dismissed. The trial court denied all of these motions. On the Statute of Limitations issue, the trial court also granted plaintiffs' cross motions, dismissing defendants' affirmative defenses that the actions were time barred. The Appellate Division affirmed in all respects and certified to this court the questions of whether the orders of the trial court were properly made. We answer these questions in the affirmative.

II.

In a products liability action, identification of the exact defendant whose product injured the plaintiff is, of course, generally required (*see, e.g., Morrissey v Conservative Gas Corp.*, 285 AD 825, *affd* 1 NY 2d 741; Prosser & Keeton, Torts § 103, at 713 [5th ed]). In DES cases in which such identification is possible, actions may proceed under established principles of products liability (*Bichler v Lilly Co., supra* at 579). The record now before us, however, presents the question of whether a DES plaintiff may recover against a DES manufac-

turer when identification of the producer of the specific drug that caused the injury is impossible.

A.

As we noted in *Bichler v Lilly Co.* (*supra* at 580, n5), the accepted tort doctrines of alternative liability and concerted action are available in some personal injury cases to permit recovery where the precise identification of a wrongdoer is impossible. However, we agree with the near unanimous views of the high State courts that have considered the matter that these doctrines in their unaltered common-law forms do not permit recovery in DES cases (*see, e.g., Sindell v Abbott Labs, supra*; *Collins v Lilly & Co.*, 116 Wis2d 166, 342 NW2d 37; *Martin v Abbott Labs, supra*; *but see, Abel v Lilly & Co.*, 418 Mich 311, 343 NW2d 164 [held that there was a question of fact presented as to alternative liability and concerted action]).

The paradigm of alternative liability is found in the case of *Summers v Tice* (33 Cal2d 80, 199 P2d 1). In *Summers* (*supra*), plaintiff and the two defendants were hunting, and defendants carried identical shotguns and ammunition. During the hunt, defendants shot simultaneously at the same bird, and plaintiff was struck by bird shot from one of the defendants' guns. The court held that where two defendants breach a duty to the plaintiff, but there is uncertainty regarding which one caused the injury, "the burden is upon such actor to prove that he has not caused the harm" (Restatement [Second] of Torts § 433B[3]; *Bichler v Lilly & Co., supra* at 580, n5; *cf., Ravo v Rogatnick*, 70 NY2d 305 [successive tortfeasors may be held jointly and severally liable for an indivisible injury to the plaintiff]). The central rationale for shifting the burden of proof in such a situation is that without this device both defendants will be silent, and plaintiff will not recover; with alternative liability, however, defendants will be forced to speak, and reveal the culpable party, or else be held jointly and severally liable themselves. Consequently, use of the alternative liability doctrine generally requires that the defendants have better access to information than does the plaintiff, and that all possible tortfeasors be before the court (*see, Summers v Tice, supra* at 86; Restatement

[Second] of Torts § 433B, comment h). It is also recognized that alternative liability rests on the notion that where there is a small number of possible wrongdoers, all of whom breached a duty to the plaintiff, the likelihood that any one of them injured the plaintiff is relatively high, so that forcing them to exonerate themselves, or be held liable, is not unfair (*Sindell v Abbott Labs*, *supra* at 139).

[5] In DES cases, however, there is a great number of possible wrongdoers, who entered and left the market at different times, and some of whom no longer exist. Additionally, in DES cases many years elapse between the ingestion of the drug and injury. Consequently, DES defendants are not in any better position than are plaintiffs to identify the manufacturer of the DES ingested in any given case, nor is there any real prospect of having all the possible producers before the court. Finally, while it may be fair to employ alternative liability in cases involving only a small number of potential wrongdoers, that fairness disappears with the decreasing probability that any one of the defendants actually caused the injury. This is particularly true when applied to DES where the chance that a particular producer caused the injury is often very remote (*Sindell v Abbott Labs*, *supra* at 603; *Collins v Lilly & Co.*, *supra* at 184). Alternative liability, therefore, provides DES plaintiffs no relief.

[6] Nor does the theory of concerted action, in its pure form, supply a basis for recovery. This doctrine, seen in drag racing cases, provides for joint and several liability on the part of all defendants having an understanding, express or tacit, to participate in "a common plan or design to commit a tortious act" (Prosser & Keeton, Torts § 46, at 323 [5th ed]; *see Bichler v Lilly & Co.*, *supra* at 580-581; *De Carvalho v Brunner*, 223 NY 284). As we noted in *Bichler v Lilly & Co.*, and as the present record reflects, drug companies were engaged in extensive parallel conduct in developing and marketing DES (*see*, *id.* at 585). There is nothing in the record, however, beyond this similar conduct to show any agreement, tacit or otherwise, to market DES for pregnancy use without taking proper steps to ensure the drug's safety. Parallel activity, without more, is insufficient to establish the agreement element necessary to

maintain a concerted action claim (*Sindell v Abbott Labs, supra* at 605; *Collins v Lilly & Co., supra* at 185; *Martin v Abbott Labs, supra* at 599). Thus this theory also fails in supporting an action by DES plaintiffs.

In short, extant common-law doctrines, unmodified, provide no relief for the DES plaintiff unable to identify the manufacturer of the drug that injured her. This is not a novel conclusion; in the last decade a number of courts in other jurisdictions also have concluded that present theories do not support a cause of action in DES cases. Some courts, upon reaching this conclusion, have declined to find any judicial remedy for the DES plaintiffs who cannot identify the particular manufacturer of the DES ingested by their mothers (*see, Zafft v Lilly & Co.*, 676 SW2d 241 [Mo] [en banc]; *Mulcahy v Lilly & Co.*, 386 NW2d 67 [Iowa] [stating that any change in the law to allow for recovery in nonidentification DES cases should come from the Legislature]). Other courts, however, have found that some modification of existing doctrine is appropriate to allow for relief for those injured by DES of unknown manufacture (*e.g., Sindell v Abbott Labs, supra*; *Collins v Lilly & Co., supra*; *Martin v Abbott Labs, supra*).

We conclude that the present circumstances call for recognition of a realistic avenue of relief for plaintiffs injured by DES. These appeals present many of the same considerations that have prompted this Court in the past to modify the rules of personal injury liability, in order "to achieve the ends of justice in a more modern context" (*see, People v Hobson*, 39 NY2d 479, 489; Codling v Paglia, 32 NY2d 330, 341), and we perceive that here judicial action is again required to overcome the " 'inordinately difficult problems of proof' " caused by contemporary products and marketing techniques (*see, Bichler v Lilly & Co., supra* at 579-580 [*quoting Caprara v Chrysler Corp.*, 52 NY2d 114, 123]).

[7] Indeed, it would be inconsistent with the reasonable expectations of a modern society to say to these plaintiffs that because of the insidious nature of an injury that long remains dormant, and because so many manufacturers, each behind a curtain, contributed to the devastation, the cost of injury should be borne by the innocent and not the wrongdoers. This

is particularly so where the Legislature consciously created these expectations by reviving hundreds of DES cases. Consequently, the ever-evolving dictates of justice and fairness, which are the heart of our common-law system, require formation of a remedy for injuries caused by DES (*see*, *Woods v Lancet*, 303 NY 349, 355; *see*, *also*, Kaye, *The Human Dimension in Appellate Judging: A Brief Reflection on a Timeless Concern*, 73 Cornell L. Rev. 1004).

We stress, however, that the DES situation is a singular case, with manufacturers acting in a parallel manner to produce an identical, generically marketed product, which causes injury many years later, and which has evoked a legislative response reviving previously barred actions. Given this unusual scenario, it is more appropriate that the loss be borne by those that produced the drug for use during pregnancy, rather than by those who were injured by the use, even where the precise manufacturer of the drug cannot be identified in a particular action. We turn then to the question of how to fairly and equitably apportion the loss occasioned by DES, in a case where the exact manufacturer of the drug that caused the injury is unknown.

B.

The past decade of DES litigation has produced a number of alternative approaches to resolve this question. Thus, in a sense, we are now in an enviable position; the efforts of other courts provided examples for contending with this difficult issue, and enough time has passed so that the actual administration and real effects of these solutions now can be observed. With these useful guides in hand, a path may be struck for our own conclusion.

First, this Court's opinion in *Bichler v Lilly & Co.* (*supra*) must be considered. There the jury was instructed on a modified version of concerted action, which, in effect, substituted the fact of conscious parallel activity by manufacturers for the usual common-law requirement that there be proof of an actual agreement between actors to jointly act tortiously (*id.* at 584). The defendant in *Bichler* did not object to this instruction, and

the modified concerted action theory became the law applicable to that particular case (*id.* at 583-584).

[8] Now given the opportunity to assess the merits of this theory, we decline to adopt it as the law of this State. Parallel behavior, the major justification for visiting liability caused by the product of one manufacturer upon the head of another under this analysis, is a common occurrence in industry generally. We believe, therefore, that inferring agreement from the fact of parallel activity alone improperly expands the concept of concerted action beyond a rational or fair limit; among other things, it potentially renders small manufacturers, in the case of DES and in countless other industries, jointly liable for all damages stemming from the defective products of an entire industry (accord, *Sindell v. Abbott Labs*, *supra* at 605).

A narrower basis for liability, tailored more closely to the varying culpableness of individual DES producers, is the market share concept. First judicially articulated by the California Supreme Court in *Sindell v Abbott Labs* (*supra*), variations upon this theme have been adopted by other courts (*see*, *Collins v Lilly & Co.*, *supra*; *Martin v Abbott Labs*, *supra*). In *Sindell v Abbott Labs* (*supra*), the Court synthesized the market share concept by modifying the *Summers v Tice* (*supra*) alternative liability rationale in two ways. It first loosened the requirement that all possible wrongdoers be before the court, and instead made a "substantial share" sufficient. The court then held that each defendant who could not prove that it did not actually injure plaintiff would be liable according to that manufacturer's market share. The court's central justification for adopting this approach was its belief that limiting a defendant's liability to its market share will result, over the run of cases, in liability on the part of a defendant roughly equal to the injuries the defendant actually caused (*id.* at 612).

In the recent case of *Brown v Superior Court* (44 Cal 3d 1049, 751 P2d 470), the California Supreme Court resolved some apparent ambiguity in *Sindell v Abbott Labs*, and held that a manufacturer's liability is several only, and, in cases in which all manufacturers in the market are not joined for any reason, liability will still be limited to market share, resulting in a less than 100% recovery for a plaintiff. Finally, it is noteworthy

that determining market shares under *Sindell v Abbott Labs* proved difficult and engendered years of litigation. After attempts at using smaller geographical units, it was eventually determined that the national market provided the most feasible and fair solution, and this national market information was compiled (*see, In re Complex DES Litig.*, No. 830/109 Cal Super Ct).

Four years after *Sindell v Abbott Labs*, the Wisconsin Supreme Court followed with *Collins v Lilly & Co.* (116 Wis 2d 166, 342 NW2d 37, *supra*). Deciding the identification issue without the benefit of the extensive California litigation over market shares, the Wisconsin court held that it was prevented from following *Sindell* due to "the practical difficulty of defining and proving market share" (*id.* at 189, 342 NW2d, at 48). Instead of focusing on tying liability closely to the odds of actual causation, as the *Sindell* court attempted, the *Collins* court took a broader perspective, and held that each defendant is liable in proportion to the amount of risk it created that the plaintiff would be injured by DES. Under the *Collins* structure, the "risk" each defendant is liable for is a question of fact in each case, with market shares being relevant to this determination (*id.* at 191, 200). Defendants are allowed, however, to exculpate themselves by showing that their product could not have caused the injury to the particular plaintiff (*id.* at 198).

The Washington Supreme Court, writing soon after *Collins v Lilly & Co.*, took yet another approach (*see, Martin v Abbott Labs*, 102 Wash 2d 581, 689 P2d 368, *supra*). The *Martin* court first rejected the *Sindell* market share theory due to the belief (which later proved to be erroneous in *Brown v Superior Court* [*supra*]) that California's approach distorted liability by inflating market shares to ensure plaintiffs of full recovery (*id.* at 601). The *Martin* court instead adopted what it termed "market share alternative liability," justified, it concluded, because "[e]ach defendant contributed to the risk of injury to the public, and consequently, the risk of injury to individual plaintiffs" (*id.* at 604, 689 P2d, at 382).

Under the Washington scheme, defendants are first allowed to exculpate themselves by proving by the preponderance of the evidence that they were not the manufacturer of the DES that

injured plaintiff. Unexculpated defendants are presumed to have equal market shares, totalling 100%. Each defendant then has the opportunity to rebut this presumption by showing that its actual market share was less than presumed. If any defendants succeed in rebutting this presumption, the liability shares of the remaining defendants who could not prove their actual market share are inflated, so that the plaintiff received a 100% recovery (*id.* at 605-606).[1] The market shares of defendants is a question of fact in each case, and the relevant market can be a particular pharmacy, or county, or state, or even the country, depending upon the circumstances the case presents (*George v Parke-Davis*, 107 Wash 2d 584, 733 P2d 507).

Turning to the structure to be adopted in New York, we heed both the lessons learned through experience in other jurisdictions and the realities of the mass litigation of DES claims in this State. Balancing these considerations, we are led to the conclusion that a market share theory, based upon a national market, provides the best solution. As California discovered, the reliable determination of any market smaller than the national one likely is not practicable. Moreover, even if it were possible, of the hundreds of cases in the New York courts, without a doubt there are many in which the DES that allegedly caused injury was ingested in another State. Among the thorny issues this could present, perhaps the most daunting is the spectre that the particular case could require the establishment of a separate

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1 The actual operation of this theory proved more mathematically complex when the court was presented with the question of what to do about unavailable defendants. Recognizing that the possibility of abuse existed when defendants implead unavailable defendants, who would then be assumed to have had an equal share of the market, the court placed the burden upon appearing defendants to prove the market share of the absent ones (*George v Parke-Davis*, 107 Wash 2d 584, 733 P2d 507). If this can be proved, the plaintiff simply cannot recover the amount attributable to the absent defendant, and thus recovery in the case is less than 100%. If the market share of the absent defendant cannot be shown, the remaining defendants who cannot prove their market shares have their shares inflated to provide plaintiff with full recovery. Finally, if all appearing defendants can prove their market shares, their shares are never inflated, regardless of whether the market share of a non-appearing defendant can be proved or not; thus, in this situation, the plaintiff again will not recover her full damages (*id.*).

market share matrix. We feel that this is an unfair, and perhaps impossible burden to routinely place upon the litigants in individual cases.

Nor do we believe that the Wisconsin approach of assessing the "risk" each defendant caused a particular plaintiff, to be litigated anew as a question of fact in each case, is the best solution for this State. Applied on a limited scale this theory may be feasible, and certainly is the most refined approach by allowing a more thorough consideration of how each defendant's actions threatened the plaintiff. We are wary, however, of setting loose, for application in the hundreds of cases pending in this State, a theory which requires the fact finder's individualized and open-ended assessment of the relative liabilities of scores of defendants in every case. Instead, it is our perception that the injustices arising from delayed recoveries and inconsistent results which this theory may produce in this State outweigh arguments calling for its adoption.

[1] Consequently, for essentially practical reasons, we adopt a market share theory using a national market. We are aware that that the adoption of a national market will likely result in a disproportion between the liability of individual manufacturers and the actual injuries each manufacturer caused in this State. Thus our market share theory cannot be founded upon the belief that, over the run of cases, liability will approximate causation in this State (*see*, *Sindell v Abbott Labs*, *supra* at 612). Nor does the use of a national market provide a reasonable link between liability and the risk created by a defendant to a particular plaintiff (see, Collins v Lilly & Co., *supra*; Martin v Abbott Labs, *supra*). Instead, we choose to apportion liability so as to correspond to the over-all culpability of each defendant, measured by the amount of risk of injury each defendant created to the public-at-large. Use of a national market is a fair method, we believe, of apportioning defendants' liabilities according to their total culpability in marketing DES for use during pregnancy. Under the circumstances, this is an equitable way to provide plaintiffs with the relief they deserve, while also rationally distributing the responsibility for plaintiffs' injuries among defendants.

To be sure, a defendant cannot be held liable if it did not participate in the marketing of DES for pregnancy use; if a DES producer satisfies its burden of proof of showing that it was not a member of the market of DES sold for pregnancy use, disallowing exculpation would be unfair and unjust. Nevertheless, because liability here is based on the over-all risk produced, and not causation in a single case, there should be no exculpation of a defendant who, although a member of the market producing DES for pregnancy use, appears not to have caused a particular plaintiff's injury. It is merely a windfall for a producer to escape liability solely because it manufactured a more identifiable pill, or sold only to certain drugstores. These fortuities in no way diminish the culpability of a defendant for marketing the product, which is the basis of liability here.[2]

Finally, we hold that the liability of DES producers is several only, and should not be inflated when all participants in the market are not before the court in a particular case. We understand that, as a practical matter, this will prevent some plaintiffs from recovering 100% of their damages. However, we eschewed exculpation to prevent the fortuitous avoidance of liability, and thus, equitably, we decline to unleash the same forces to increase a defendant's liability beyond its fair share of responsibility.[3]

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2 Various defendants argue here that although they produced DES, it was not sold for pregnancy use. If a defendant was not a member of the national market of DES marketed for pregnancy, it is not culpable, and should not be liable. Consequently, if a particular defendant sold DES in a form unsuitable for use during pregnancy, or if a defendant establishes that its product was not marketed for pregnancy use, there should be no liability. From the record before the Court here, however, the facts are not developed well enough to establish that any defendants were not in the national market of DES sold for pregnancy use. Thus summary judgment cannot at this time be granted on this issue as to any defendants.

3 The dissenter misapprehends the basis for liability here. We have not by the backdoor adopted a theory of concerted action. We avoided extending this theory, because its concomitant requirement of joint and several liability

III.

The constitutionality of the revival statute remains to be considered (*see*, L 1986, ch 682; § 4). This section revives, for the period of one year, actions for damages caused by the latent effects of DES, tungsten carbide, asbestos, chlordane, and polyvinylchloride. Defendants argue that the revival of barred DES claims was unconstitutional as a denial of both due process and equal protection, under the State and Federal Constitutions (*see*, NY Const art 1, §§ 6, 11; US Const, 14th Amend, § 1). We are concerned here only with the constitutionality of the statute as it pertains to DES; there are no producers of the other substances, or plaintiffs alleging injury therefrom, before the Court on these appeals.

The Federal Due Process Clause provides very little barrier to a State Legislature's revival of time-barred actions (*see*, *Chase*

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expands the burden on small manufacturers beyond a rational or fair limit. This result is reached by the dissent, not by the majority, so that criticism on this front is misplaced.

We are confronted here with an unprecedented identification problem, and have provided a solution that rationally apportions liability. We have heeded the practical lessons learned by other jurisdictions, resulting in our adoption of a national market theory with full knowledge that it concedes the lack of a logical link between liability and causation in a single case. The dissent ignores these lessons, and, endeavoring to articulate a theory it perceives to be closer to traditional law, sets out a construct in which liability is based upon chance, not upon the fair assessment of the acts of defendants. Under the dissent's theory, a manufacturer with a large market share may avoid liability in many cases just because it manufactured a memorably shaped pill. Conversely, a small manufacturer can be held jointly liable for the full amount of every DES injury in this State simply because the shape of its product was not remarkable, even though the odds, realistically, are exceedingly long that the small manufacturer caused the injury in any one particular case.

Therefore, although the dissent's theory based upon a "shifting the burden of proof" and joint and several liability is facially reminiscent of prior law, in the case of DES it is nothing more than advocating that bare fortuity be the test for liability. When faced with the novel identification problem posed by DES cases, it is preferable to adopt a new theory that apportions fault rationally, rather than to contort extant doctrines beyond the point at which they provide a sound premise for determining liability.

Sec. Corp v Donaldson, 325 US 304). In *Chase*, the United States Supreme Court upheld the revival of a time barred action, stating that Statutes of Limitation "represent a public policy about the privilege to litigate * * * the history of pleas of limitation shows them to be good only by legislative grace and to be subject to a relatively large degree of legislative control" (*id.* at 314). Under State law, the level of review seems somewhat more stringent. In *Gallewski v Hentz & Co.* (301 NY 164, 174) the Court stated that "the Legislature may constitutionally revive a personal cause of action where the circumstances are exceptional and are such as to satisfy the Court that serious injustice would result to plaintiffs not guilty of any fault if the intentions of the Legislature were not effectuated." It appears, however, that we have applied a less strict test in other cases, and have been satisfied if there was an apparent injustice which "calls for a remedy," and which is "reasonable" and not "arbitrary." (*Robinson v Robbins Dry Dock & Repair Co.*, 238 NY 271, 279-280).

We need not light upon a precise test here, however, because the Legislature's revival of DES claims meets the highest standard. For at least 25 years this Court maintained an exposure rule for toxic substances, because it was felt that change in this area was the responsibility of the Legislature (*see, e.g., Schwartz v Heyden Newport Chem. Corp.*, 12 NY2d 212, 220; *Fleishman v Lilly & Co.*, *supra* at 890). Indeed, in *Fleishman v Lilly & Co.* (*supra*) the Legislature's attention was drawn specifically to DES by the majority, which stated that any change in the exposure rule was the Legislature's role.

[2] The Legislature has now revived DES actions that were time barred under the exposure rule, while also instituting a discovery rule for future application (L 1986, ch 682, § 4; CPLR 214-c). The latent nature of DES injuries is well known, and it is clear that in the past the exposure rule prevented the bringing of timely actions for recovery. Thus we believe that exceptional circumstances are presented, that an injustice has been rectified, and that the requirements of *Gallewski v Hentz & Co.* (*supra*) have been met.

[3] Defendants argue further that, even if the statute is generally valid, it may be unconstitutionally applied in cases in

which the plaintiff could have sued originally, but did not. It does seem that some plaintiffs may have known of their injuries a day, or a week, a month, or perhaps longer, before the original limitations period ran. Some may have known of their exposure, but did not develop injuries during the limitations period. Others may have known of some effect upon them of DES exposure, which became cancerous only after any action would have been time barred. Under these circumstances, the Legislature properly determined that it would be more fair for all plaintiffs to uniformly now have one year to bring their actions, rather than for the courts to begin drawing arbitrary lines transecting this area's shades of gray.

[4] Defendants also argue that the revival statute violates equal protection, because the Legislature designated only five substances for revival, including DES, while instituting a prospective only discovery rule for other substances. Defendants claim that this categorization is without sufficient basis, and that it is the result of a "political compromise." But most, if not all legislation is the product of some compromise, so that this objection surely is no basis for finding the revival statute unconstitutional. Instead, here we must proceed on the presumption that the law is constitutional, and will hold otherwise only if it is established that the distinction drawn has no reasonable basis (*Trump v Chu*, 65 NY2d 20; *Montgomery v Daniels*, 38 NY2d 41, 61). Moreover, because defendants allege no impairment of a fundamental right, the Legislature has substantial leeway in making classifications in this area of " 'economics and social welfare' " (*see*, *Montgomery v Daniels*, *supra*, [*quoting Dandridge v Williams*; 397 US 471, 485]).

As it pertains to DES, surely the revival statute has a rational basis, and the Legislature acted within its broad range of discretion in enacting the law. The number of DES-caused injuries was relatively well known by the Legislature, which allowed for the ramifications of revival of DES claims, such as the effect on insurance interests, and the other costs, to be reasonably predicted (Record of Proceedings, New York Assembly [June 24, 1986] [statement of Assemblyman M. H. Miller]). Furthermore, it was also well known, particularly after *Fleishman v Lilly & Co.* (*supra*), that DES victims were prejudiced under

current law. This, we believe, is enough of a basis for the Legislature to revive DES claims now, and wait as to other substances until it is felt that these substances present a problem suitable for resolution. The Legislature does not violate equal protection by providing a rational piecemeal remedy for what may be a larger problem (*Williamson v Lee Opt. Co.*, 348 US 483).

Accordingly, in each case the order of the Appellate Division should be affirmed, with costs, and the certified question answered in the affirmative.

MOLLEN, J. (concurring in *Hymowitz* and *Hanfling*; and dissenting in part in *Tigue* and *Dolan*). The issue presented to the court in this appeal is to determine whether the revival statute for DES claims is constitutional and has properly "opened the window" to enable injured parties to recover for their injuries caused by DES and, if so, how to best enable such plaintiffs to overcome the practical impossibility of bearing their normal burden of proof of demonstrating that the defendants caused their injuries. The majority has selected one approach to meet this issue. However, I am compelled to concur in part and dissent in part because I am convinced that another more appropriate method of approaching this issue is fairer and more just and equitable to the plaintiffs and to those defendants who could not have caused the plaintiff's injuries, and which is consistent with established principles tort law. I concur with the majority's conclusion that the revival statute is, in all respects, constitutional and may be relied upon by the plaintiffs herein. I am also in complete agreement with the majority's view that the market share theory of liability, based upon a national market, is an appropriate means by which to accord DES plaintiffs an opportunity to seek recovery for their injuries. However, I respectfully disagree with the majority's conclusion that there should be no exculpation of those defendants who produced and marketed DES for pregnancy purposes, but who can prove, by a preponderance of the evidence, that they did not produce or market the particular pill ingested by the plaintiff's mother.

Moreover, in order to ensure that these plaintiffs receive full recovery of their damages, as they are properly entitled to by any fair standard, I would retain the principle of imposing joint and several liability upon those defendants which cannot exculpate themselves.

The emergence of the market share concept of liability in the field of products liability reflects a recognition by several jurisdictions throughout the United States that due to the incidence of mass production and marketing of various drugs and fungible goods, consumers are many times harmed by a product which is not easily traceable to a specific manufacturer, particularly in those situations where the harm occurred many years prior to the discovery of the injuries and the cause thereof. Such is the situation in the DES cases now before us. Under traditional common-law tort principles, a plaintiff is required to establish the existence of a causal relationship between the act or omission of the defendant or defendants and the injury sustained (*see*, *Morrissey v Conservative Gas Corp.*, 1 NY2d 741; Prosser & Keeton, Torts § 41, at 263 [5th ed.]). However, given the reality of the situation in DES cases, including the lengthy passage of time, the generic form of most DES pills and the unavailability of pharmaceutical and physician records, it is, as a practical matter, impossible for most DES plaintiffs to bear the burden of proof of establishing the traditional tort element of causation.

Moreover, as noted by the majority, the tort doctrines of alternative liability and concerted action, both of which provide for recovery in situations where a plaintiff, through no fault of his or her own, cannot identify the actual wrongdoer, do not provide appropriate relief to these DES plaintiffs. Unlike the scenario present in the DES cases, the principle of alternative liability presupposes that the number of possible wrongdoers are few in number, that one of the joined defendants had to have actually caused the plaintiff's injury and that the defendants are in a much better position than the plaintiff to identify the actual wrongdoer and, therefore, the burden is shifted to the defendants to prove who was the actual wrongdoer and who among them are to be exculpated (*see*, *Summers v Tice*, 33 Cal 2d 80, 199 P2d 1; Restatement [Second] of Torts 433B[3]).

However, in view of the difference in the factual circumstances, the theory of alternative liability does not provide a workable solution for DES plaintiffs.

The concept of concerted action liability requires, *inter alia*, that the plaintiff prove that all of the joined defendants had an understanding, expressed or implied, to participate in a common plan or design to commit a tortiuos act or to lend assistance to the wrongdoer (*see*, Prosser & Keeton, Torts § 46, at 323 [5th ed.]). Typically, DES plaintiffs allege that the concerted action of the DES manufacturers consisted of using one another's marketing techniques, relying upon each other's testing and encouraging one another to market DES without performing adequate testing or warnings. The courts, with few exceptions (*see, e.g., Abel v Lilly & Co.*, 418 Mich 311, 343 NW2d 164), have rejected the applicability of concerted action liability to DES cases because the plaintiffs cannot establish the existence of an express or tacit agreement among DES manufacturers to market or produce DES without proper testing or warnings (*see, e.g., Sindell v Abbott Labs*, 26 Cal 3d 588, 607 P2d 924, *cert denied* 499 US 912; *Martin v Abbott Labs*, 102 Wash 2d 581, 689 P2d 368; *Collins v Lilly & Co.*, 116 Wis 2d 166, 342 NW2d 37). The parallel or imitative conduct of DES manufacturers in producing and/or marketing DES, as the majority expressly notes, is insufficient, in and of itself, to establish concerted action liability (majority opn, at 506).

The principle of market share liability in DES litigation was first espoused by the California Supreme Court in *Sindell v Abbott Labs* (*supra*), as a valid theory of manufacturer's liability based upon each manufacturer's share of the market. This approach provides DES plaintiffs with a means by which to recover damages for their injuries without the plaintiffs being held to the traditional tort requirement of identifying the actual wrongdoer. The public policy underpinnings of the *Sindell* rationale is that, from a perspective of fairness and equity, the DES manufacturers are in a better position than the innocent plaintiffs who have sustained grievous injuries to bear the cost of such injuries. Thus, the *Sindell* court held that once a plaintiff has joined a "substantial share" of the DES manufacturers of the relevant market in the action and has established that the

sustained injuries were caused by the ingestion of DES by the plaintiff's mother during pregnancy, the burden of proof shifts to each defendant to demonstrate, by a preponderance of the evidence, that it did not produce or market the pill ingested by the plaintiff's mother. Those DES defendants who could not exculpate themselves, would then be liable for the proportion of the judgment which represented its share of the market. The intended result of the *Sindell* approach is that, "each manufacturer's liability for an [particular DES] injury would be approximately equivalent to the damage caused by the DES it manufactured" (*supra*, p 613, 607 P2d, at 938).

The Wisconsin and Washington Supreme Courts subsequently adopted collective liability theories in DES cases based upon similar policy considerations; namely, as between the injured plaintiffs and the negligent defendants, the latter should bear the cost of injury (*Collins v Lilly Co.*, 116 Wis 2d 166, 342 NW2d 37, *supra*; *Martin v Abbott Labs*, 102 Wash 2d 581, 689 P2d 368, *supra*). Both the *Collins* and *Martin* courts reasoned that since all of the DES manufacturers and distributors contributed to the risk of injury to the public and, consequently, the risk of injury to individual plaintiffs, each defendant shared, in some measure, a degree of culpability in producing or marketing DES. In *Collins*, the Wisconsin Supreme Court adopted a "risk contribution" theory of liability, and, in *Martin*, the Washington Supreme Court adopted what it termed a "market share alternative liability" theory. These two approaches differ from the *Sindell* theory primarily in the manner in which the damages are apportioned. Significantly, both the Supreme Courts of Wisconsin and Washington in the *Collins* and *Martin* cases, as did the Supreme Court of California in *Sindell*, provided that the joined or impleaded defendants may exculpate themselves from liability if they can establish, by a preponderance of the evidence, that they did not produce or market the particular DES pill taken by the plaintiff's mother. Notably, in *Collins*, the Wisconsin Supreme Court explained that it would not adopt a risk contribution theory which would have imposed liability solely upon the DES defendants' participation in the creation of the risk of injury even though some of the defendants could establish that they could not have actually

caused the plaintiff's injury. The *Collin's* court noted, "[W]e still require it be shown that the defendant drug company reasonably could have contributed in some way to the actual injury" (*supra*, p 191, n 10, 342 NW2d, at 49, n 10). In fact, *none* of the jurisdictions which have adopted varying theories of collective liability in DES cases, has refused to permit exculpation of those defendants which have been able to prove that they could not have produced or marketed the pill which caused the particular plaintiff's injuries, thereby recognizing that to preclude exculpation would directly and unnecessarily contravene the established common-law tort principles of causation (*see, Sindell v Abbott Labs, supra*; *Collins v Lilly & Co., supra*; *Martin v Abbott Labs, supra*; *Abel v Lilly & Co., supra*; *McCormack v Abbott Labs*, 617 F Supp 1521, *see also, Burnside v Abbott Labs*, 351 Pa Super 264, 505 A2d 973).

Clearly, the development and underlying purpose of the various concepts of liability in DES cases has been to provide a means whereby the plaintiffs, who cannot identify the actual manufacturer of the pill ingested by their mother, are alleviated of the traditional burden of proof of causation and to shift that burden to the defendants. The various theories of collective liability which have been adopted in the several jurisdictions in an effort to provide plaintiffs with a means to recovery for their injuries, were not intended to, and did not, provide DES plaintiffs with an unprecedented strict liability cause of action. However, the majority herein, by precluding exculpation of those defendants in DES cases who produced DES for pregnancy purposes but who can establish, by a preponderance of the evidence, that they did not and could not have produced or marketed the pill which caused the plaintiff's injuries, has created such a radical concept and purports to limit it to DES claims. In the majority's view, the defendant's liability in DES cases is premised upon the overall risk or injury which they created to the public-at-large in producing and marketing DES for pregnancy purpose and, therefore, exculpation of those defendants who can establish that the plaintiff's mother did not ingest their pill, would be inconsistent with the overall risk theory of liability. By taking this view, however, the majority, while stating that it is adopting a market share theory of liabil-

ity, is, in essence, despite its disclaimer of doing so, adopting a concerted action theory of liability, but has eliminated therefrom the requirement that the plaintiffs establish that the defendants tacitly agreed to produce and market DES for pregnancy use without proper testing and without adequate warnings of the potential dangers involved. Such a result, represents a radical departure from fundamental tenets of tort law and is unnecessarily unfair and inequitable to the defendants who have proven, or can prove, that they did not produce the pill which caused the injury. Moreover, this result is directly contrary to the majority's own statement that it is rejecting the "conscious parallelism" theory utilized in *Bichler v Lilly & Co.* (79 AD2d 317, *affd* 55 NY2d 571), because, as stated by the majority herein, "(p)arallel behavior, the major justification for visiting liability by the product of one manufacturer upon the head of another under this analysis, is a common occurrence in industry generally. We believe, therefore, that inferring agreement from the fact of parallel activity alone improperly expands the concept of concerted action beyond a rational or fair limit; among other things, it potentially renders small manufacturers in the case of DES and in countless other industries, jointly liable for all the damages stemming from the defective products of an entire industry" (majority opn, at 508-509).

I fully concur with the above-stated position of the majority and thus, I cannot agree that the imposition of liability on drug companies, in this case DES manufacturers, solely upon their contribution, in some measure, to the risk of injury by producing and marketing a defective drug, without any consideration given to whether the defendant drug companies actually caused the plaintiff's injuries, is appropriate or warranted. Rather, I would adopt a market share theory of liability, based upon a national market, which would provide for the shifting of the burden of proof on the issue of causation to the defendants and would impose liability upon all of the defendants who produced and marketed DES for pregnancy purposes, except those who were able to prove that their product could not have caused the injury. Under this approach, DES plaintiffs, who are unable to identify the actual manufacturer of the pill ingested by their mother, would only be required to establish, (1) that the plain-

tiff's mother ingested DES during pregnancy; (2) that the plaintiff's injuries were caused by DES; and (3) that the defendant or defendants produced and marketed DES for pregnancy purposes. Thereafter, the burden of proof would shift to the defendants to exculpate themselves by establishing, by a preponderance of the evidence, that the plaintiff's mother could not have ingested their particular pill. Of those defendants who are unable to exculpate themselves from liability, their respective share of the plaintiff's damages would be measured by their share of the national market of DES produced and marketed for pregnancy purposes during the period in question.

I would further note that while, on the one hand, the majority would not permit defendants who produced DES for pregnancy purposes to exculpate themselves, the majority at the same time deprives the plaintiffs of the opportunity to recover fully for their injuries by limiting the defendants' liability for the plaintiff's damages to several liability. In my view, the liability for the plaintiff's damages of those defendants who are unable to exculpate themselves should be joint and several thereby ensuring that the plaintiffs will receive full recovery of their damages. In addition to being fair to the DES plaintiffs, the imposition of joint and several liability is consistent with that portion of the revival statute which specifically exempted DES claims from those provisions which provide, with certain exceptions, for several liability of joint tortfeasors (*see*, L. 1986, ch. 682, § 12; CPLR § 1600 *et seq.*). Moreover, in order to ease the financial burden on the specific defendants named in the lawsuit, the defendants would have the option of seeking contribution from their fellow defendants for damages in excess of each defendant's particular market share, and a defendant should be permitted leave to implead those DES manufacturers who the plaintiff has not joined, in order to ensure, where possible, full contribution (*see, e.g.*, *Dole v Dow Chemical Co.*, 30 NY2d 143). Admittedly, adherence to joint and several liability could result in a disproportion between a defendant's potential liability for the damages suffered by the plaintiff and defendant's actual national market share; however, the opportunity to present exculpatory evidence reduces the risk of imposing liability on innocent defendants.

The application of the aforesaid principles, although somewhat innovative and a modification of traditional tort law, (i.e., the burden of proof is on the plaintiff to prove proximate causation) would, in view of the exigent circumstances, be in furtherance of a valid public policy of imposing the burden of bearing the cost of severe injuries upon those who are responsible for placing into the stream of commerce the causative instrumentality of such injuries. Adherence to this principle would not be too dissimilar from the accepted doctrine of *res ipsa loquitor* which provides, in essence, that where an instrumentality which caused the plaintiff's injuries was in the exclusive control of the defendant and the accident which occurred is one which would not ordinarily happen without negligence, these facts are sufficient to justify an inference of negligence and to shift the burden upon the defendant of coming forward with an explanation (*see, e.g., Galbraith v Busch*, 267 NY 230, 234; Richardson, Evidence § 93, at 68 [Prince 10th ed]). Thus, this approach, unlike that taken by the majority, does not represent an unnecessary and radical departure from basic principles of tort law. By characterizing this approach as "nothing more than advocating that bare fortuity be the test for liability" (majority opn, at 513, n 3) the majority fails to perceive that this is no more and no less than a basic principle of tort law; i.e., a plaintiff may not recover for his or her injuries from a defendant who could not have caused those injuries. When the majority eliminates this fundamental causative factor as a basis for recovery, it effectively indulges in the act of judicial legislating. I would further note that if the Legislature had intended to adopt this radical approach which is at total variance with traditional tort law, it could readily have done so when it enacted the revival statute for, among others, DES plaintiffs. Its refusal to do so can certainly not be deemed to be an invitation to this court to assume the legislative role.

Judged by the aforesaid standard, I conclude that the trial courts' orders in *Tigue & Margolies v E.R. Squibb* (decided herewith) and *Dolan v Eli Lilly* (decided herewith), to the extent that they denied the summary judgment motions of the defendant The Upjohn Company ("Upjohn") in both actions and the defendant Rexall Drug Company ("Rexall") in the *Tigue*

action, were improper. In *Tigue*, Mrs. Tigue, the plaintiff's mother, testified that the DES pill she ingested while she was pregnant with the plaintiff was a white, round tablet (record on app, at 709-710). Similarly, Myrna Margolies' mother testified that the DES pill she ingested was a dark red, hard, round pill (*id.*, at 224-226). Mr. Margolies, the plaintiff's father, also recalled that the pills were a reddish color and Mrs. Margolies' obstetrician stated that the DES pill he prescribed to his patients was not an Upjohn product. Moreover, in the *Dolan* action, Mrs. Dolan, the plaintiff's mother, stated that the DES pill she took was a white, round, hard tablet (*id.*, at 321, 303). This fact was corroborated by Mr. Dolan's testimony (*id.*, at 414, 444). Finally, it was established that Upjohn's DES pill which was produced and marketed for pregnancy purposes, was in the form of a "perle" which is a pharmaceutical term for a dose form consisting of a soft elastic capsule containing a liquid center (*id.*, at 2182). Based on the evidence submitted in support of Upjohn's summary judgment motions in these two cases, I would conclude that the plaintiffs have failed to adduce sufficient proof in admissible form to raise a triable issue of fact as to whether their mothers ingested an Upjohn DES pill. Accordingly, Upjohn's motion for summary judgment in those actions should have been granted.

Additionally, in *Tigue & Margolies v E.R. Squibb* (decided herewith), Rexall's motion for summary judgment should have been granted since the plaintiffs failed to raise a triable issue of fact as to whether their mothers could have ingested a Rexall DES product during the pregnancies in question. The evidence submitted in support of Rexall's motion established that until 1978, Rexall sold its products, including its DES pill, *exclusively* to Rexall Drug Stores (record, at 1934, 22003-04; 2210). The testimony of the plaintiffs' parents, Mrs. Tigue and Mr. and Mrs. Margolies established that they had purchased their DES prescriptions from non-Rexall pharmacies during the periods of their respective pregnancies, i.e., 1960 and 1953. Based on this uncontroverted evidence demonstrating Rexall's noninvolvement in these plaintiffs' injuries, Rexall's motion for summary judgment should have been granted.

As to those defendants which seek to exculpate themselves from liability in these various actions based upon the fact that they produced and marketed DES solely for non-pregnancy purposes, we agree with the majority's conclusion that the record before the Court is factually insufficient to establish that they were not in the national market of DES sold for pregnancy use (*see*, majority opn, at 512, n 2). Accordingly, their summary judgment motions were properly denied.

At a term of the Appellate Division of the Supreme Court held in and for the First Judicial Department in the County of New York, on April 14, 1988

Present Hon.: Theodore R. Kupferman, Justice Presiding
Sidney H. Asch
Ernst H. Rosenberger
Betty Weinberg Ellerin
George Bundy Smith, Justices.

31980

Elizabeth Tigue, Barbara Tigue, Sayre Margolies, as Administratrix of the Estate of Myrna Margolies,

Plaintiffs-Respondents,

—against—

E.R. Squibb & Sons, Inc., Abbott Laboratories, Boyle & Company Pharmaceuticals, Merck Sharp & Dohme, a Division of Merck & Co., Inc., Rexall Drug Company, William H. Rorer, Inc. and The Upjohn Company,

Defendants-Appellants,

Amfre-Grant Inc., a Subsidiary of Ormont Drug & Chemical Co., Inc., Carnrick Laboratories, a Division of G.W. Carnrick Co., Cole Pharmacal Company, Inc., Kremers-Urban Company, and Jerome Schneider, M.D.,

Defendants.

An appeal having been taken to this Court by the defendants-appellants from an order of the Supreme Court, New York County (Ira Gammerman, J.), entered on July 23, 1987, which

denied appellants' motions, pursuant to CPLR 3212 for summary judgment dismissing the plaintiffs' complaint.

And said appeal having been argued by John L. McGoldrick of counsel for appellant Abbott Laboratories, by A. Edward Grashof of counsel for appellant Rexall Drug Company, by Jay P. Mayesh of counsel for appellant The Upjohn Company, by William K. Dodds of counsel for appellant Boyle & Company Pharmaceuticals, by Joseph DiBenedetto of counsel for appellant Rorer Pharmaceutical Corp., f/k/a William H. Rorer, Inc., by Roy G. Weatherup of counsel for appellant E.R. Squibb & Sons, Inc., by Theodore V.H. Mayer of counsel for appellant Merck Sharp & Dohme, a Division of Merck & Co., Inc., and by Paul D. Rheingold of counsel for respondents; and due deliberation having been had thereon, and upon the memorandum decision of this Court filed herein,

It is unanimously ordered that the order so appealed from be and the same hereby is affirmed, without costs and without disbursements.

ENTER:

HAROLD J. REYNOLDS
Clerk.

MEMORANDUM DECISION OF THE APPELLATE DIVISION OF THE SUPREME COURT OF THE STATE OF NEW YORK: FIRST DEPARTMENT

Elizabeth Tigue, et al., Respondents, v. E.R. Squibb & Sons, Inc., et al., Appellants, et al., Defendants.—Order, Supreme Court, New York County (Ira Gammerman, J.), entered July 23, 1987, denying the motions of defendants Rexall, Upjohn and Abbott, pursuant to CPLR 3212, for summary judgment dismissing the plaintiffs' complaints, unanimously affirmed, without costs.

Seven drug manufacturers appeal from a well-reasoned determination which denied exculpation based on their claim that they were not the manufacturer of the drug known as diethlystilbestrol (DES), allegedly ingested by the mothers of the plaintiffs. The history of DES is well documented in a previous opinion of this court, *Bichler v Eli Lilly and Co.* (79 AD2d 317).

The underlying problem presented is which of the many manufacturers of this unpatented drug should be held culpable, where it cannot be definitively determined which company manufactured the pills ingested by the plaintiffs' mothers.

In the 1987 Cumulative Supplement to his treatise, 1 New York Products Liability Sec. 8:07, Michael Weinberger succinctly analyzes the present state of the law under the heading "Enterprise Liability":

"In Bichler v. Eli Lilly & Co.,* the Court of Appeals affirmed a plaintiff's verdict, which was based on a concerted action theory. However, the Court did *not* decide the validity of a cause of action based on concerted action in DES cases. The court stated that because defendant did not object to the trial court's instructions on concerted action, this theory became the law of the case, and was not preserved for appellate review. Hence, the court took no position on the question of whether New York recognizes a cause of action based on concerted action.

"In a later related DES case, the Court of Appeals again took *no* position on whether the theory of concerted action (or other related theories) should be adopted in DES cases. The court held only that the Bichler jury finding of concerted action was

not entitled to collateral estoppel effect, because the issue of concerted action was not actually contested in the trial judge's jury charge in the earlier case.** Therefore, New York still has no position on whether a cause of action in DES cases can be based on concerted action.

"* 9.50 Bichler v. Eli Lilly & Co., 55 NY2d 571, 450 NYS2d 776, 436 NE2d 182 (1982)

"** 9.60 Kaufman v. Eli Lilly & Co., 65 NY2d 449, 492 NYS2d 584, 482 NE2d 63 (1985)."

As noted by Justice Gammerman, the law in this department clearly recognizes the concerted action theory. (*Bichler v Lilly & Co., supra*, 79 AD2d at 328-29.) There is, however, still a question of whether exculpation is available to those drug manufacturers who can clearly establish that they could not have been the purveyor of the drug to a particular plaintiff, which question is also significant in the many other DES cases presently pending in the courts. For example, it was testified that hard, small, white tablets were ingested by Mrs. Tigue. It is contended that because a different colored pill was marketed, there is no liability. Another defendant contends that it sold only to its licensed franchisees and, therefore, inasmuch as the pills in question were purchased at a specific pharmacy which was not one of its franchisees, there should be no liability. Another defendant postulates that it did not sell in the east and so could not have been the purveyor to these plaintiffs. Still another defendant contends that it did not market DES for pregnancy-related purposes.

Basic to any determination is the question of whether exculpation should be permitted at all. However, in view of the fact that the Court of Appeals has, in two instances, left the question of concerted action open, we should now permit a complete trial record to be developed, so that when the matter is finally determined, there will be no question as to the factual details. Concur—Kupferman, J.P., Asch, Rosenberger, Ellerin and Smith, JJ. [See, 136 Misc 2d 467.]

SUPREME COURT OF THE STATE OF NEW YORK
[ILLEGIBLE]
at the Courthouse thereof, 60 Centre Street
New York, New York, 10007.
Present: Hon. _____
Justice.

ELIZABETH TIGUE, ET AL.,

—against—

E.R. SQUIBB & SONS, INC., ET AL.,

I.A.S. PART
PAPERS SUBMITTED
JUL 20 1987

NUMBERED _____

Upon the foregoing papers this motion is decided in accordance with accompanying memorandum.

FILED
JUL 23 1987
COUNTY CLERK'S OFFICE
NEW YORK

Dated 7/16/87 /s/ IG
J.S.C.

Briefs _____

County Clerk's No. 3838, 1976

ELIZABETH TIGUE, et al., *Plaintiffs*, v. E.R. SQUIBB & SONS, INC., et al., *Defendants*.

OPINION OF THE COURT

IRA GAMMERMAN, J.:

Defendants Rexall Drug Company (Rexall), The Upjohn Company (Upjohn) and Abbott Laboratories (Abbott) move pursuant to CPLR 3212 for summary judgment dismissing the complaint based upon the conceded inability of plaintiffs to identify the particular manufacturer of the drug, diethylstibestrol, (DES) to which they were allegedly exposed. Defendants contend that the right to recover on collective, nonidentification or concerted action theories of liability has not been established in New York and urge the court to reject adoption of such theories. Defendants further contend that if concerted action is a viable basis of liability, it should not be applicable in a DES case. The motions are consolidated for disposition.

Plaintiffs seek to recover for injuries allegedly sustained by Elizabeth Tigue and Myrna Margolies (now deceased) as a result of the ingestion of DES by their mothers. Sayre Margolies proceeds on behalf of her daughter Myrna who died in 1977 at age 23, from clear cell adenocarcinoma of the cervix and vagina, a rare form of cancer in young women, associated with prenatal exposure to DES. Plaintiff Elizabeth Tigue was diagnosed as having vaginal adenosis, a precancerous condition associated with DES exposure, in which glandular tissue normally found in the cervix is found in the vagina. Plaintiffs' complaints allege breach of warranty, negligence, strict liability, res ipsa loquitur, concerted action and aiding and abetting strict liability.

HISTORICAL BACKGROUND:

DES is a synthetic hormone that duplicates the function of estrogen, a female sex hormone naturally present in women and, in lesser amounts, in men. Estrogen is essential for female sexual development and reproduction. DES was first synthesized in 1937 by British medical researchers. The drug was never patented, and thus, could be produced and marketed in the

United States by any company obtaining Food and Drug Administration (FDA) approval of a New Drug Application (NDA).

By 1940, ten drug companies had filed NDAs requesting approval to produce and market DES for treatment of menopause, senile vaginitis, gonorrheal vaginitis and suppression of lactation. None of the conditions for which this initial approval was sought related to pregnancy. These filings were rejected by the FDA, it determining that the review process would be facilitated by the pooling of clinical data produced by the drug companies into a master file which would form the data base for the FDA decision. In 1941, twelve pharmaceutical companies formed the "Small Committee"* to pool this clinical data for submission to the FDA. The joint clinical data was incorporated in each company's resubmitted NDA and in September, 1941, FDA approval was obtained for the use of DES. The Small Committee was thereafter disbanded.

In 1947 and 1948 a number of drug manufacturers filed supplemental NDAs for authorization to market DES, now for the treatment of certain pregnancy disorders relating to spontaneous abortion or fetal death. The dosage proposed for this treatment was many times stronger than the dosage previously approved in 1941. The supplemental applications were primarily based upon studies by two independent researchers on the role of hormones in pregnancy. The researchers reported that the administration of additional estrogen in certain high-risk pregnancies appeared to reduce the risk of miscarriage. The FDA approval for use of the drug in pregnancy was then given.

LACK OF PRODUCT IDENTIFICATION:

The fundamental issue raised here (and the major problem facing these and many other plaintiffs in these DES cases) is their inability to identify the manufacturer of the DES taken by

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* The twelve companies were: Abbott; Armour Laboratories; Ayerst, McKenna & Harrison, Ltd.; Geo. A. Breon & Co., Inc.; Charles E. Frost & Co.; Eli Lilly & Co.; Merck & Co., Inc.; Sharpe & Dohme, Inc.; E. R. Squibb & Sons; Upjohn Winthrop Chemical Company; and John Wyeth & Brothers, Inc.

the mothers of the injured women and, thus, to directly connect the injury to a particular defendant.

The DES taken by pregnant women was produced under a chemically identical formula and usually manufactured and prescribed generically. Apparently, many drug companies cannot locate or have failed to keep records of their DES market activity. Although that market was dominated by a small number of companies, entry and exit from the market was fluid and it is estimated that between 94 and 300 pharmaceutical companies manufactured or marketed DES from 1947 to 1971.

Injuries caused by prenatal exposure to DES appear many years later. Over time, the ability of a plaintiff to identify the manufacturer is, obviously, greatly reduced. The memories or records of those who could assist in identifying the manufacturer (parents, physicians, pharmacists and drug companies) fade or disappear.

PRIOR HOLDINGS:

In this State, the general rule is that a plaintiff has the burden of proof on product identification (*Morrissey v. Conservative Gas Corp.*, 285 App Div 825 [1955], *aff'd*, 1 NY2d 741 [1956]). However, several nonidentification or collective liability theories have been proposed and in some cases adopted, to deal with cases in which the manufacturer of a product cannot be identified.

In *Bichler v. Lilly & Co.*, (79 AD2d 317 [1st Dept. 1981], *aff'd*, 55 NY2d 571 [1982]), a theory of concerted action liability was the basis of recovery even though the defendant was not identified as the manufacturer of the particular DES taken by the plaintiff's mother. Indeed in *Bichler*, the jury found that the plaintiff had not established that Lilly manufactured the DES taken by her mother.

Two theories of concerted action were submitted to the jury: concerted action by implied agreement and concerted action by substantial assistance. The jury was instructed that concerted action by agreement could be inferred from evidence of consciously parallel actions, that such consciously parallel action could be the basis of a finding that the drug companies had

impliedly agreed to market DES for pregnancy use without first testing the drug on pregnant mice. The trial court's charge with respect to concerted action by substantial assistance permitted the jury to find that the failure to test DES on pregnant mice by defendant Lilly substantially aided or encouraged other companies (including, presumably, the company that marketed the DES taken by plaintiff's mother) to market without appropriate testing.

The jury found that Lilly had acted in concert, that the failure to test was wrongful and that the injurious effects of DES were foreseeable. On appeal to the Appellate Division, defendant argued that the trial court's concerted action charge was erroneous, an argument that the court addressed on its merits.

The Appellate Division found sufficient evidence to support the jury's findings and, in effect, adopted the concerted action theory of liability charged by the trial court. When *Bichler* (*supra*) reached the Court of Appeals, a determination was made that Lilly had failed to properly except to the trial court's charge on concerted action and concerted action liability was applicable only as the law of the case. The court concluded that there was adequate evidence to support concerted action liability by conscious parallelism or substantial assistance. The Court of Appeals (unlike the trial court and the Appellate Division) based its finding solely on events beginning in 1947 (formation of identical chemical standards, marketing DES without testing on pregnant mice, reliance upon the same studies to support supplemental NDAs) and indicated that the 1941 collaboration to secure approval for nonpregnancy use, had no bearing upon concerted action relating to the 1947 supplemental NDA for pregnancy use (*Bichler v. Lilly & Co.*, 55 NY2d 571, 585, n.7 *supra*).

In *Kaufman v. Lilly & Co.*, (65 NY2d 449, 456), the court stated: "we expressed no view in *Bichler* and, express none now, on which of the proposed theories — concerted action, alternative liability, enterprise liability or market share liability — if any, should be adopted in this or similar DES cases (*see*, *Bichler v. Lilly & Co.*, *supra*, at p. 580, n.5). The question is still an open one in New York."

DISCUSSION:

Defendants correctly contend that the applicability of the various "collective liability" theories (including concerted action) to DES fact patterns has not been finally ruled upon by the Court of Appeals. Nevertheless, the First Department clearly recognized and expressly adopted the concerted action theory for DES cases (*Bichler v. Lilly & Co.*, 79 AD2d 317; *Kaufman v. Lilly & Co.*, 99 AD2d 695; *see, Carrao v. Heitler*, 117 AD2d 308, 313).

Since plaintiffs, at least in this department, may proceed on a collective or concerted action liability theory, the inability to identify the actual manufacturer of the DES taken by Mrs. Tigue and Mrs. Margolies is not fatal. Plaintiffs' factual allegations to support a finding of concerted action are substantially the same as those pleaded in *Bichler* (*supra*) and clearly state a viable cause of action for concert by agreement or substantial assistance.

As in *Bichler* (*supra*), plaintiffs contend that a finding of concert by conscious parallelism or substantial assistance may be supported based upon the formation of identical chemcial standards for DES in pregnancy, the marketing of the drug without prior testing on pregnant mice and the drug companies' reliance upon the same studies in supplemental NDAs. Plaintiffs also rely on defendants' activities leading to the FDA approval for nonpregnancy use based upon the contention that their supplemental NDAs relied upon the earlier filing. Whether the request for approval of DES for use in pregnancy relied upon the earlier filings presents an issue of fact which cannot be determined on a motion for summary judgment. Similarly, defendant's claims that the actions by the drug companies in gaining FDA approval of DES (whether for nonpregnancy or pregnancy use) and their actions with regard to the manufacture, marketing and distribution of DES for use in pregnancy constitute concerted action sufficient to impose liability are questions for the trier of fact.

In addition, plaintiffs apparently seek to impose industry-wide liability based upon wrongful failure to test and subsequent generic marketing and dispensing of DES. Plaintiffs'

basic theory is that "but for the development, manufacture, distribution and sale of DES by the defendants, plaintiffs would not have suffered the injuries which they have suffered."

Plaintiffs contend that under their "but for" analysis, in addition to concert, they would be permitted to recover under various non-identification theories: enterprise liability (*Hall v. DuPont de Nemours & Co.*, 345 F Supp 353 [ED NY 1972]); alternative liability; market share liability (*Sindell v. Abbott Labs.*, 26 Cal 3d 588, 163 Cal Rptr 132, 607 P2d 924 *cert. denied*, 449 U.S. 912); risk contribution (*Collins v. Lilly Co.*, 116 Wis 2d 166, 342 NW2d 37 *cert. denied sub nom. Squibb & Sons v. Collins*, 469 U.S. 826).

This Court declines to rule at this time on the applicability to DES cases of each of the various theories of liability (in addition to concerted action), which are not specifically pleaded but are raised in response to defendants' motions. The only question raised on the motions before this court is whether defendants may be held liable absent product identification and the answer is yes.

CLAIMS OF EXCULPATION:

Defendants Rexall and Upjohn contend that under any collective liability theory, a defendant who can establish that its product could not have caused plaintiff's injury may exculpate itself from liability. While exculpation may be theoretically possible (certainly under market share liability), even if the product of a particular manufacturer could be excluded a defendant may bear legal responsibility based on joint activity, encouragement or assistance in bringing a harmful product into the stream of commerce.

CONSTITUTIONAL ATTACK:

Rexall further contends that any theory of liability (including judicially established tort doctrines) under which liability may be imposed without "causation-in-fact", presumably product identification, is unconstitutional as an excessive burden on interstate commerce and violative of the Due Process and Equal Protection Clauses. Further, it argues, that imposing market

share and enterprise liability frustrate expressed federal policies regarding the marketing of prescription drugs and thus violate the Supremacy Clause.

Defendant Rexall's due process challenges are unpersuasive. Under the various theories discussed above, the requirement of traditional product identification is merely relaxed based on a finding that each defendant by its tortious behavior caused or contributed to plaintiff's injuries. Under these theories, liability may be premised upon the tortious behavior of each defendant, whose adherence to a course of conduct resulting in an unsafe standard, perpetuates the standard.

Fundamentally, imposition of liability absent product identification is based on policy grounds. As a matter of equity, the tort-feasor (who is in the best position to absorb the cost and to take the precautions) rather than the innocent victim, should bear the cost of injury. Defendants can be held responsible for wrongful conduct or omissions that result in placing a generic/fungible harmful product on the market.

Rexall's equal protection challenge amounts to no more than a fairness argument which does not rise to constitutional proportions. Equal protection is not synonymous with absolute equality (*see, Dandridge v. Williams*, 397 US 471; *People v. Parker*, 41 NY2d 21; *Parker 86th Assocs. v. City of New York*, 93 AD2d 388, *aff'd*, 59 NY2d 986).

Rexall's federal preemption claim also lacks merit. "The criteria for determining whether there has been federal preemption are (1) the pervasiveness of the federal regulation, (2) the dominance of the federal interest, (3) the federal and state objectives to be obtained, and (4) the existence of actual conflict between the state and federal statutes, including whether the state law is an obstacle to the purposes and objectives of Congress" (*Pharmaceutical Socy. v. Lefkowitz*, 586 F2d 953, 958 [2d Cir., 1978]). Application of these criteria precludes a finding of Federal preemption. The primary objective of the Federal law is controlling product safety and efficacy (*supra*, at 958). The objective of the proposed theories of recovery is basic fairness, to provide a remedy to the innocent victims of wrongdoers.

Rexall contends that the imposition of liability without product identification burdens interstate commerce, by increasing

the cost of products, reducing availability and limiting sales by discouraging development of new drugs, and by generally increasing the cost of doing business thereby precluding entry into the pharmaceutical business.

In determining whether there is an undue burden on interstate commerce, the test is whether " 'the burden * * * on [interstate] commerce is clearly excessive in relation to the putative local benefits' " (*Pharmaceutical Socy. v. Lefkowitz, supra*, at 957, *quoting Pike v. Bruce Church*, 397 US 137, 142). Here, the local benefit is providing a forum to innocent victims of alleged wrongdoing by relaxing the traditional product identification requirement in tort law. Clearly, a legitimate State interest is furthered. While adoption of a nonidentification theory of liability could conceivably burden interstate commerce to the extent that the cost of such increased liability would be passed on to consumers through higher prices," not every exercise of local power is invalid merely because it affects in some way the flow of commerce between the States" (*A & P Tea Co. v. Cottrell*, 424 US 366, 371). Rexall has failed to demonstrate that the burden here would be clearly excessive compared to the benefit. Therefore, the Commerce Clause challenge also must fail.

Accordingly, defendants' motions for summary judgment dismissing the complaint are denied, and the matter is set down for trial on September 30, 1987.

To Be Argued By:
A. EDWARD GRASHOF
Time Requested: 20 minutes

New York County Clerk's Index No. 03838/76

Court of Appeals
STATE OF NEW YORK

ELIZABETH TIGUE, BARBARA TIGUE, SAYRE MARGOLIES, as Administratrix of the Estate of MYRNA MARGOLIES,

Plaintiffs-Respondents,

—against—

E. R. SQUIBB & SONS, INC., ABBOTT LABORATORIES, BOYLE & COMPANY PHARMACEUTICALS, MERCK SHARP & DOHME, Division of MERCK & CO., INC., REXALL DRUG COMPANY, and THE UPJOHN COMPANY,

Defendants-Appellants,

—and—

AMFRE-GRANT, INC., a Subsidiary of ORMONT DRUG & CHEMICAL CO., INC., CARNRICK LABORATORIES, Division of G.W. CARNRICK CO., COLE PHARMACAL COMPANY, INC., KREMERS-URBAN COMPANY, WILLIAM H. RORER, INC., and JEROME SCHNEIDER, M.D.,

Defendants.

BRIEF OF DEFENDANT-APPELLANT REXALL DRUG COMPANY

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STATEMENT OF QUESTIONS INVOLVED

* * *

2. Is it constitutional to impose liability without fault on a defendant, who owed no duty to plaintiff and did not cause plaintiff's injury, merely because that defendant manufactured a product similar to the one that allegedly caused plaintiff's injury?

The Appellate Division did not address this question.

* * *

IV

ANY THEORY OF LIABILITY IN THE DES CASES THAT DOES NOT REQUIRE PROOF OF IDENTIFICATION OF THE ALLEGED TORTFEASOR AND THUS IMPOSES LIABILITY WITHOUT FAULT VIOLATES THE DUE PROCESS GUARANTEES OF THE UNITED STATES AND NEW YORK CONSTITUTIONS

A. Imposition of Liability in the DES Cases Without Proof of Identification of the Tortfeasor Violates Substantive Due Process By Creating an Arbitrary, Unreasonable and Capricious Rule of Law

The due process clause of the Fourteenth Amendment to the United States Constitution and Section 6 of Article 1 of the New York State Constitution protects individuals against any deprivation of liberty or property which does not meet the standards of due process. *Giaccio v. Pennsylvania*, 382 U.S. 399, 402 (1966); *Modjeska Sign Studios, Inc. v. Berle*, 43 N.Y.2d 468 (1977), *appeal dismissed*, 439 U.S. 809 (1978). The protection of the due process clause "is not to be avoided by the simple label a state chooses to fasten upon its conduct or Statute." *Giaccio v. Pennsylvania*, 382 U.S. at 402. And it extends to protecting an individual from arbitrary decisions by judges or juries. *Id. See also NAACP v. Alabama*, 377 U.S. 288, 307-08 (1964); *Wright v. Georgia*, 373 U.S. 284, 291 (1963); *Reece v. Georgia*, 350 U.S. 85, 89 (1955).

The limits of due process are provided by the laws of logic. *In re Japanese Electronic Products Antitrust Litigation*, 723 F.2d at 304. Hence, to pass muster under the due process clause, there must be a rational relation between the means chosen and the end pursued. *See, e.g., United States v. Carolene Products Co.*, 304 U S. 144, 154 (1938).

Theories of liability which eliminate the element of identification from plaintiffs' *prima facie* case and impose liability simply because a DES manufacturer cannot prove it did not cause the alleged injuries, allocate fault based not on logic, but on speculation and conjecture. *Graber-Bittel v. Eli Lilly & Co.*, slip op. at 6-7; *Enright v. Eli Lilly & Co.*, slip op. at 17; *Ryan v. Eli Lilly & Co.*, 514 F. Supp. at 1008; *Tidler v. Eli Lilly & Co.*, 95 F.R.D. at 334. There is nothing logical about imposing liability on a randomly selected group of DES manufacturers as there is no rational basis to conclude that even one of them is the alleged tortfeasor. In such circumstances, the imposition of liability does not come close to satisfying the minimum rationality test enunciated in *United States v. Carolene Products Co.*, 304 U.S. at 154. Indeed two courts in this State have explicitly recognized the irrationality of the *Bichler* concerted action theory, denouncing it as "unjust", "not rational or reasonable," and founded on "Robin Hood logic" of taking from the solvent and giving to the unfortunate. *Graber-Bittel v. Eli Lilly & Co.*, slip op. at 6-7; *Enright v. Eli Lilly & Co.*, slip op. at 17.

B. Elimination of the Identification Element From Plaintiff's *Prima Facie* Case Violates Due Process in that it Effects an Uncompensated Taking

Creation of theories of liability which abrogate the causation element effect a direct and government sponsored taking of private property by compelling innocent defendants to bear the cost of injuries for which they are not responsible. Individuals cannot be required to shoulder an undue or arbitrary share of a public burden without just compensation, nor can a court take the property of one DES manufacturer to pay for the liability of another. *See Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 160 (1980); *Armstrong v. United States*, 364 U.S.

40, 49 (1960); *Road Improv. Dist. v. Missouri P. R. Co.*, 274 U.S. 188, 194 (1927).

A judicially created subsidy in this case would be an unconstitutional taking of property, particularly with regard to Rexall which has demonstrated that it did not injure the plaintiffs herein. *See Enright v. Eli Lilly & Co.*, slip op. at 17. As the District Court stated in *Tidler v. Eli Lilly & Co.*:

> Joining the manufacturers of a 'substantial share', whatever that phrase means, of the DES introduced into some 'market' provides no statistical or mathematical assurance that any defendant, in fact, bore any responsibility for the plaintiff's injuries. Thus, the DES ingested by any particular plaintiff's mother may not have come from any of the defendants in this case. *Such a result suggests possible constitutional difficulties of taking property without due process of law*, unless the Congress or a legislative body could enact a law with some rational basis or nexus which would withstand constitutional scrutiny.

95 F.R.D. at 334, n.5.

The unconstitutionality of theories of liability which eliminate proof of causation was also enunciated in *State, to Use of Maines v. A/S Nye Kristianborg*, 84 F. Supp. 775 (D. Md. 1949).

> It requires no elaboration to demonstrate that a statute which, as we have seen, would impair a property right, by subjecting one's property to the claims of another, without personal fault or legal liability of the owner, destroys vested rights of property, and is therefore clearly invalid. *It is a taking of property without due process of law contrary to the 14th Amendment of the Federal Constitution* . . . .

Id. at 780.

C. Imposition of Liability in the DES Cases Without Proof of Identification of the Tortfeasor Violates Procedural Due Process Because It Creates An Irrebuttable, Irrational and Unreasonable Presumption of Causation

Irrebuttable presumptions have long been disfavored under the due process clause. *Vlandis v. Kline*, 412 U.S. 441, 446 (1973). Such presumptions are "offensive to due process because they effectively deny an individual the essential right to challenge the purported factual basis of a determination adversely affecting his own liberty or property." *Hurley v. Van Lare*, 380 F. Supp. 167, 175 (S. and E.D.N.Y 1974), *vacated*, 421 U.S. 338 (1975) (three judge district court). *Cf. People v. DeJesus*, 122 Misc. 2d 190, 192 (Sup. Ct. N.Y. Co. 1983) (due process demands that procedures be available to give voice to "claims of infirmity" of presumption so as to be able to overcome same). Yet, in a DES case, by eliminating proof of identification from plaintiff's *prima facie* case and shifting the burden of identification to defendants, a court would have effectively created an irrebuttable presumption of causation since defendants are in no better position than plaintiffs on the element of proof. Indeed, most defendants are in a worse position than plaintiffs. *See infra* p. 64.

In order for such a presumption to withstand due process, it must be neither unreasonable nor irrational. *See, e.g., United States Dept. of Agriculture v. Murry*, 413 U.S. 508, 514 (1973). Such a presumption must also be "universally true in fact" in order to be valid under the due process clause. *Vlandis v. Kline*, 412 U.S. at 441. Yet, as a number of courts have recognized in the DES context, any theory which shifts the burden to defendants to disprove causation creates an irrational and unreasonable presumption of liability because there is no certainty that any one or more of the defendants joined in an action produced the drug in question. *Graber-Bittel v. Eli Lilly & Co.*, slip op. at 6-7; *Enright v. Eli Lilly & Co.*, slip op. at 17; *Ryan v. Eli Lilly & Co.*, 514 F. Supp. at 1018; *Mizell v. Eli Lilly & Co.*, 526 F. Supp. 589, 596 (D.S.C. 1981); *Tidler v. Eli Lilly & Co.*, 95 F.R.D. at 333.

* * *

VI

PLAINTIFFS' CLAIMS AGAINST REXALL ARE PREEMPTED BY FEDERAL LAW AND REGULATIONS

For almost fifty years, all drugs sold in the United States have been required to submit to an approval process pursuant to the Congressional mandate embodied in the Federal Food, Drug, and Cosmetic Act of 1938 (the "Act"). The FDA, the federal agency charged with enforcement of the Act, has been recognized as "the most effective national drug regulatory agency in the world." Stulley, *Assuring the Safety and Efficacy of Therapies*, 4 Int'l J. of Health Services 131, 142 (1974). The FDA "probably requires the most careful drug safety testing of any regulatory agency in the world." Simmons, *The Drug Regulatory System of the United States Food and Drug Administration*, 4 Int'l J. of Health Services 95, 97 (1974).

DES could not have been marketed without the approval of the FDA. The approval process included not only the submission of data from rigorous chemical tests and clinical studies to establish the safety and efficacy of the drug and approval of proposed labeling and accompanying literature but also the FDA's own investigation and study of the drug. *See* pp. 28-29, supra. As stated in *Gray v. United States*, 445 F. Supp. 337 (S.D. Tex. 1978) where the court rejected a suit against the United States for its role in approving DES for use in treatment of accidents of pregnancy:

> Congress has chosen the FDA to be the decision maker in this area, and its judgments in approving [DES] as safe for use must be beyond private scrutiny and litigation.

Id. at 340.

The Supremacy Clause of the United States Constitution states that federal law is the supreme law of the land and that judges are bound by it, notwithstanding state law to the contrary. U.S. Const. art. VI. cl. 2.

Federal law has been defined to include not only the United States Constitution, federal statutes and treaties, but also fed-

eral regulations promulgated by federal agencies. *See Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984); *Fidelity Federal Savings and Loan Association v. De La Cuesta*, 458 U.S. 141, 153 (1982). State law has also been defined broadly to include not only state constitutions, statutes and regulations, but also state common law tort liability decisions. *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959). *See also Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202 (1985) (state tort claim held preempted by national labor laws); *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 187 (3d Cir. 1986), *cert. denied*, 479 U.S. 1043 (1987) (the Federal Cigarette Labeling and Advertising Act preempts state law damage actions relating to smoking and health).

While one begins with a presumption that federal law is not intended to displace state law, *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981), that presumption is rebutted by demonstrating either express or implied preemptive intent. Express intent is not at issue herein since the Act itself is silent as to its effect on state law regulation of drugs.

From this silence, however, it cannot be inferred that states may enter any area of drug regulation. *See, e.g., Pharmaceutical Soc. of State of New York v. Lefkowitz*, 586 F.2d 953 (2d Cir. 1978) (the initial determination, and subsequent control in the marketplace, of the safety and efficacy of drugs are functions of the FDA which states are barred from regulating).

The preemptive intent of the Act as to state law tort claims may be established by implication. Such intent may be inferred from four separate factors: (1) the content and legislative history of a federal statute; (2) the public policy behind a federal law; (3) the pervasiveness of federal law; or (4) the existence of a direct conflict between state and federal law. *See KVUE, Inc. v. Moore*, 709 F.2d 922, 931-32 (5th Cir. 1983), *aff'd sub. nom. Texas v. KVUE, Inc.*, 465 U.S. 1092 (1984). Evidence of preemptive intent demonstrated by any one of these factors will suffice to preempt any state regulations to the contrary.

The FDA's control over the manufacture and approval of DES was pervasive and complete, and the federal interest in

drug regulation is dominant over state interests and calls for uniform national regulation. The federal regulatory scheme set forth in the Act and its regulations thus preempt any state law which frustrates the objectives of the Act. Accordingly, the Court should hold that plaintiffs' claims are barred by the doctrine of preemption. *But see Hurley v. Lederle Laboratories*, 851 F.2d 1536 (5th Cir 1988).

* * *

CONCLUSION

For the reasons indicated, Defendant Rexall Drug Company respectfully requests that the Order appealed from be reversed and that summary judgment be granted at least as to it on each and every claim asserted in Plaintiffs' Amended Complaint.

Dated: New York, New York
November 4, 1988

Respectfully submitted,

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To Be Argued By:
A. EDWARD GRASHOF

New York County Clerk's Index No. 03838/76

New York Supreme Court

APPELLATE DIVISION—FIRST DEPARTMENT

ELIZABETH TIGUE, BARBARA TIGUE, SAYRE MARGOLIES, as Administratrix of the Estate of MYRNA MARGOLIES,

Plaintiffs-Respondents,

—against—

E. R. SQUIBB & SONS, INC., ABBOTT LABORATORIES, BOYLE & COMPANY PHARMACEUTICALS, MERCK SHARP & DOHME, Division of MERCK & CO., INC., REXALL DRUG COMPANY, WILLIAM H. RORER, INC., and THE UPJOHN COMPANY,

Defendants-Appellants,

—and—

AMFRE-GRANT, INC., a Subsidiary of ORMONT DRUG & CHEMICAL CO., INC., CARNRICK LABORATORIES, Division of G.W. CARNRICK CO., COLE PHARMACEUTICAL COMPANY, INC., KREMERS-URBAN COMPANY, and JEROME SCHNEIDER, M.D.,

Defendants.

BRIEF OF DEFENDANT-APPELLANT REXALL DRUG COMPANY

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SHEILA M. FESSLER

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STATEMENT OF QUESTIONS INVOLVED

* * *

4. Is the imposition of liability upon one whom no one can identify as the manufacturer of the product which allegedly injured plaintiff so arbitrary, unreasonable and irrational as to violate United States and New York constitutional guarantees of due process?

The court below answered this question in the negative.

5. Does the pervasive federal regulation of manufacturers of pharmaceutical products by the United States Food and Drug Administration pursuant to the mandate of the Federal Food, Drug and Cosmetic Act of 1938 preempt state law tort claims arising out of precisely those matters regulated by that federal agency?

The court below answered this question in the negative.

* * *

IV

ANY THEORY OF LIABILITY IN THE DES CASES THAT DOES NOT REQUIRE PROOF OF IDENTIFICATION OF THE ALLEGED TORTFEASOR AND THUS IMPOSES LIABILITY WITHOUT FAULT VIOLATES THE DUE PROCESS GUARANTEES OF THE UNITED STATES AND NEW YORK CONSTITUTIONS

A. Imposition of Liability in the DES Cases Without Proof of Identification of the Tortfeasor Violates Substantive Due Process By Creating an Arbitrary, Unreasonable and Capricious Rule of Law

The due process clause of the Fourteenth Amendment to the United States Constitution and Section 6 of Article 1 of the New York State Constitution protects individuals against any deprivation of liberty or property which does not meet the standards of due process. *Giaccio v. Pennsylvania*, 382 U.S. 399, 402 (1966); *Modjeska Sign Studios, Inc. v. Berle*, 43 N.Y.2d 468

(1977), *appeal dismissed*, 439 U.S. 809 (1978). The protection of the due process clause "is not to be avoided by the simple label a state chooses to fasten upon its conduct or Statute." *Giaccio v. Pennsylvania*, *supra*, 382 U.S. at 402. And it extends to protecting an individual from arbitrary decisions by judges or juries. *Id. See also NAACP v. Alabama*, 377 U.S. 288, 308 (1964); *Wright v. Georgia*, 373 U.S. 284, 291 (1963); *Reece v. Georgia*, 350 U.S. 85, 89 (1955).

The limits of due process are provided by the laws of logic. *See* pp. 35-36, *supra*. Hence, to pass muster under the due process clause, there must be a rational relation between the means chosen and the end pursued. *See, e.g., United States v. Carolene Products Co.*, 304 U.S. 144, 154 (1938).

Theories of liability which eliminate the element of identification from plaintiffs' *prima facie* case and impose liability simply because a DES manufacturer cannot prove it did not cause the alleged injuries, allocate fault based not on logic, but on speculation and conjecture. *Ryan v. Eli Lilly & Co.*, *supra*, 514 F. Supp. at 1008; *Tidler v. Eli Lilly & Co.*, *supra*, 95 F.R.D. at 334. There is nothing logical about imposing liability on a randomly selected group of DES manufacturers as there is no rational basis to conclude that even one of them is the alleged tortfeasor. In such circumstances, the imposition of liability does not come close to satisfying the minimum rationality test enunciated in *United States v. Carolene Products Co.*, *supra*, 304 U.S. at 154.

B. Elimination of the Identification Element From Plaintiff's *Prima Facie* Case Violates Due Process in that it Effects an Uncompensated Taking

Creation of theories of liability which abrogate the causation element effect a direct and government sponsored taking of private property by compelling innocent defendants to bear the cost of injuries for which they are not responsible. Individuals cannot be required to shoulder an undue or arbitrary share of a public burden without just compensation, nor can a court take the property of one DES manufacturer to pay for the liability of

another. *See Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 160 (1980); *Armstrong v. United States*, 364 U.S. 40, 49 (1960); *Road Improv. Dist. v. Missouri P. R.R. Co.*, 274 U.S. 188, at 194 (1927).

A judicially created subsidy in this case would be an unconstitutional taking of property, particularly with regard to Rexall which has demonstrated that it did not injure the plaintiffs herein. As the District Court stated in *Tidler v. Eli Lilly & Co.*, *supra*, 95 F.R.D. 332:

> "Joining the manufacturers of a 'substantial share', whatever that phrase means, of the DES introduced into some 'market' provides no statistical or mathematical assurance that any defendant, in fact, bore any responsibility for the plaintiff's injuries. Thus, the DES ingested by any particular plaintiff's mother may not have come from any of the defendants in this case. *Such a result suggests possible constitutional difficulties of taking property without due process of law*, unless the Congress or a legislative body could enact a law with some rational basis or nexus which would withstand constitutional scrutiny."

Id. at 334, n.5.

The unconstitutionality of theories of liability which eliminate proof of causation was also enunciated in *State Use of Maine v. A/S Nye Kristianborg*, 84 F. Supp. 775 (D. Md. 1949).

> It requires no elaboration to demonstrate that a statute which, as we have seen, would impair a property right, by subjecting one's property to the claims of another, without personal fault or legal liability of the owner, destroys vested rights of property, and is therefore clearly invalid. *It is a taking of property without due process of law contrary to the 14th Amendment of the Federal Constitution* . . . .

Id. at 780.

C. Imposition of Liability in the DES Cases Without Proof of Identification of the Tortfeasor Violates Procedural Due Process Because It Creates An Irrebuttable, Irrational and Unreasonable Presumption of Causation

Irrebuttable presumptions have long been disfavored under the due process clause. *Vlandis v. Kline*, 412 U.S. 441, 446 (1973). Such presumptions are "offensive to due process because they effectively deny an individual the essential right to challenge the purported factual basis of a determination adversely affecting his own liberty or property." *Hurley v. Van Lare*, 380 F. Supp. 167, 175 (S. and E.D.N.Y. 1974) (three judge district court). *Cf. People v. DeJesus*, 122 Misc. 2d 190, 192 (Sup. Ct. N.Y. Co. 1983) (due process demands that procedures be available to give voice to "claims of infirmity" of presumption so as to be able to overcome same). Yet, in a DES case, by eliminating proof of identification from plaintiff's *prima facie* case and shifting the burden of identification to defendants, a court would have effectively created an irrebuttable presumption of causation since many defendants are in no better position than plaintiffs on the element of proof. Indeed, most defendants are in a worse position than plaintiffs. *See* pp. 44-45, *supra*.

In order for such a presumption to withstand due process, it must be neither unreasonable nor irrational. *See, e.g., United States Dept. of Agriculture v. Murry*, 413 U.S. 508, 514 (1973). Such a presumption must also be "universally true in fact" in order to be valid under the due process clause. *Vlandis v. Kline*, *supra*, 412 U.S. at 441. Yet, as a number of courts have recognized in the DES context, any theory which shifts the burden to defendants to disprove causation creates an irrational and unreasonable presumption of liability because there is no certainty that any one or more of the defendants joined in an action produced the drug in question. *Ryan v. Eli Lilly & Co.*, *supra*, 514 F. Supp. at 1018; *Mizell v. Eli Lilly & Co.*, *supra*, 526 F. Supp. at 596; *Tidler v. Eli Lilly & Co.*, *supra*, 95 F.R.D. 333.

V

PLAINTIFFS' CLAIMS AGAINST REXALL ARE PREEMPTED BY FEDERAL LAW AND REGULATIONS

For almost fifty years, all drugs sold in the United States have been required to submit to an approval process pursuant to the Congressional mandate embodied in the Federal Food, Drug, and Cosmetic Act of 1938 (the "Act"). The FDA, the federal agency charged with enforcement of the Act, has been recognized as "the most effective national drug regulatory agency in the world." Stulley, *Assuring the Safety and Efficacy of Therapies*, 4 Int'l J. of Health Services 131, 142 (1974). The FDA "probably requires the most careful drug safety testing of any regulatory agency in the world." Simmons, *The Drug Regulatory System of the United States Food and Drug Administration*, 4 Int'l J. of Health Services 95, 97 (1974).

As described in Squibb's factual summary, DES could not have been marketed without the approval of the FDA. The approval process included not only the submission of data from rigorous chemical tests and clinical studies to establish the safety and efficacy of the drug and approval of proposed labeling and accompanying literature but also the FDA's own investigation and study of the drug. *See* pp. 28-29, *supra*. As stated in *Gray v. United States*, 445 F. Supp. 337 (S.D. Tex. 1978) where the court rejected a suit against the United States for its role in approving DES for use in treatment of accidents of pregnancy:

> Congress has chosen the FDA to be the decision maker in this area, and its judgments in approving [DES] as safe for use must be beyond private scrutiny and litigation.

Id. at 340.

In their complaint, however, plaintiffs allege that defendants breached duties under state law to develop a safer drug, failed to test the drug adequately, and breached an implied warranty. These causes of action attack the very findings of the FDA which permitted the drug to be marketed in the first place. To permit the prosecution of these causes of action would be to

ignore the stringent FDA standards and to allow courts and juries to formulate their own requirements and impose them retroactively on drug manufacturers on a case by-case basis. The doctrine of federal preemption precludes this result.

The Supremacy Clause of the United States Constitution states that federal law is the supreme law of the land and that judges are bound by it, notwithstanding state law to the contrary. U.S. Const. art. VI, cl. 2.

Federal law has been defined to include not only the United States Constitution, federal statutes and treaties, but also federal regulations promulgated by federal agencies. *See Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984); *Fidelity Federal Savings and Loan Association v. De La Cuesta*, 458 U.S. 141, 153 (1982). State law has also been defined broadly to include not only state constitutions, statutes and regulations, but also state common law tort liability decisions. *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959). *See also Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202 (1985) (state tort claim held preempted by national labor laws); *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 187 (3d Cir. 1986), *cert. denied*, 109 S. Ct. 907 (1987) (the Federal Cigarette Labeling and Advertising Act preempts state law damage actions relating to smoking and health).

While one begins with a presumption that federal law is not intended to displace state law, *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981), that presumption is rebutted by demonstrating either express or implied preemptive intent. Express intent is not at issue herein since the Act itself is silent as to its effect on state law regulation of drugs.

From this silence, however, it cannot be inferred that states may enter any area of drug regulation. *See, e.g., Pharmaceutical Soc. of State of New York v. Lefkowitz*, 586 F.2d 953 (2d Cir. 1978) (the initial determination, and subsequent control in the marketplace, of the safety and efficacy of drugs are functions of the FDA which states are barred from regulating).

The preemptive intent of the Act as to state law tort claims may be established by implication. Such intent may be inferred from four separate factors: (1) the content and legislative history of a federal statute; (2) the public policy behind a federal law; (3) the pervasiveness of federal law; or (4) the existence of a direct conflict between state and federal law. *See KVUE, Inc. v. Moore*, 709 F.2d 922, 931-32 (5th Cir. 1983), *aff'd sub nom. Texas v. KVUE, Inc.*, 465 U.S. 1092 (1984). Evidence of preemptive intent demonstrated by any one of these factors will suffice to preempt any state regulations to the contrary.

* * *

CONCLUSION

Defendant Rexall Drug Company respectfully requests that the July 23 Order appealed from be reversed and that it be granted summary judgment on each and every claim asserted in Plaintiffs' Amended Complaint.

Dated: New York, New York
November 16, 1987

Respectfully submitted,

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